Investigational Drug Branch
Drug Development Plan Tool version 2.1
User Training Document

January 24, 2001

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IDB Drug Development Plan Tool Purpose

- Use MS Project to visually represent the temporal data stored in CTEP's enterprise database
- Allow IDB drug monitors and TRI clinical research experts to easily display, review, and share information about clinical trial milestones and accruals

IDB Drug Development Plan Tool Training Goals

Teach individual users how to:

- Find, start, and log on to the tool
- Select clinical trial protocols and letters of intent with the tool
- Chart clinical trial milestones with the tool
- Read Gantt chart symbols and notes
- Add notes and user-defined tasks to a Gantt chart
- Print and save a Gantt chart
- Report problems and ask questions about the tool

Training Scenario Overview

A Clinical Research Specialist (CRS) with TRI receives a clinical trial Quarterly Report from a principal investigator. The CRS uses the IDB Drug Development Plan Tool to accomplish the following:

- Review amendment dates for the clinical trial
- Communicate information about responses and phase II solicitations to the IDB Monitor
- Print and save charts for later discussion of the the trial's progress

Training Information Conventions

Three types of information are presented in the training scenario. Each type of information appears in a different type of box.

Scenario Element:
Information about what is happening in the scenario appears in this type of box with this type of text.

Tool Use
Information about how to use the tool features appears in this type of box with this type of text.

Technical Info
Information about the technology behind the tool appears in this type of box with this type of text.

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Scenario Elements

NOTE: All scenario elements are hypothetical!

Scenario Element:

A Principal Investigator submits a Quarterly Report for the Phase I trial T97-0118.

Scenario Element:

A CRS at TRI reviews the Quarterly Report and notes the following information:

- **Two patients are showing response to the agent**
- **The study is reaching Maximum Tolerated Dose**

Scenario Element:

The CRS decides that some of this information should be communicated to the IDB Drug Monitor for the study.

Investigational Drug Branch
Drug Development Plan Tool

Selecting and Charting a Study

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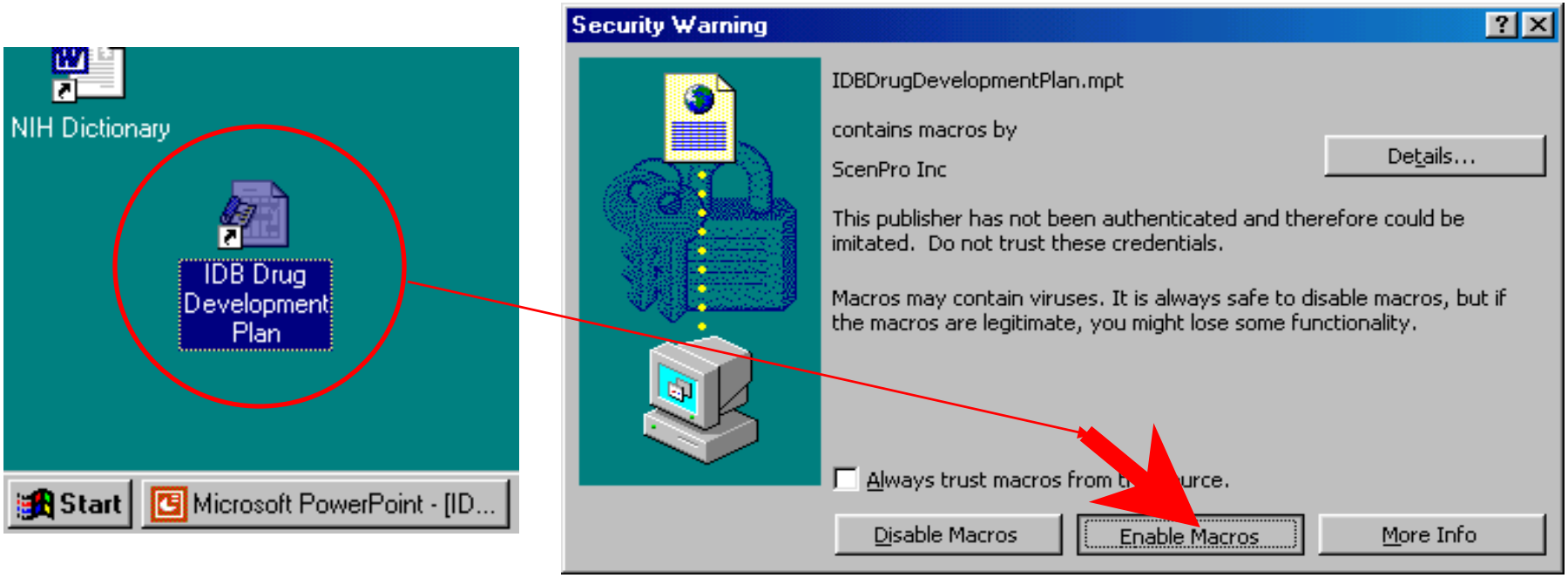
Starting the Tool via the Desktop Shortcut



Scenario Element:

The CRS opens the IDB Drug Development Plan Tool by double-clicking on the desktop icon and by enabling macros if prompted .

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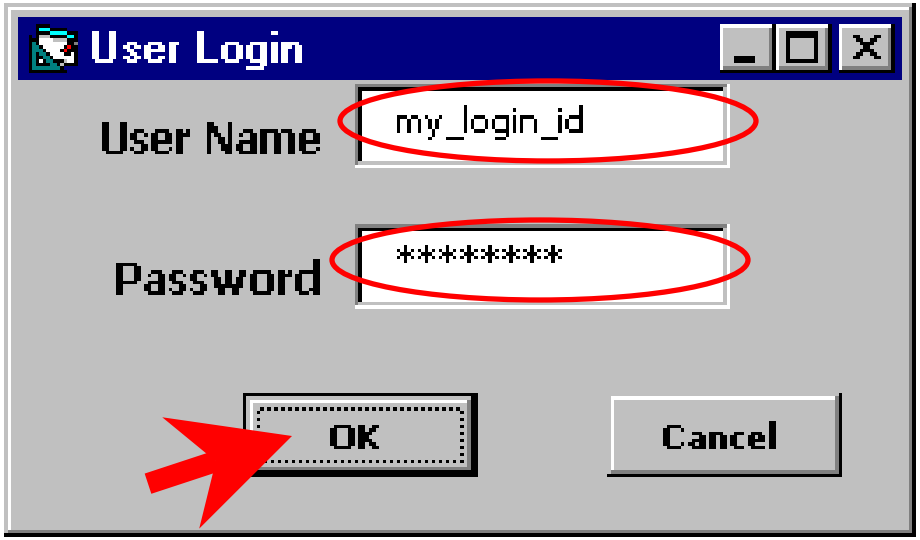
Logging on to the Database

Scenario Element:

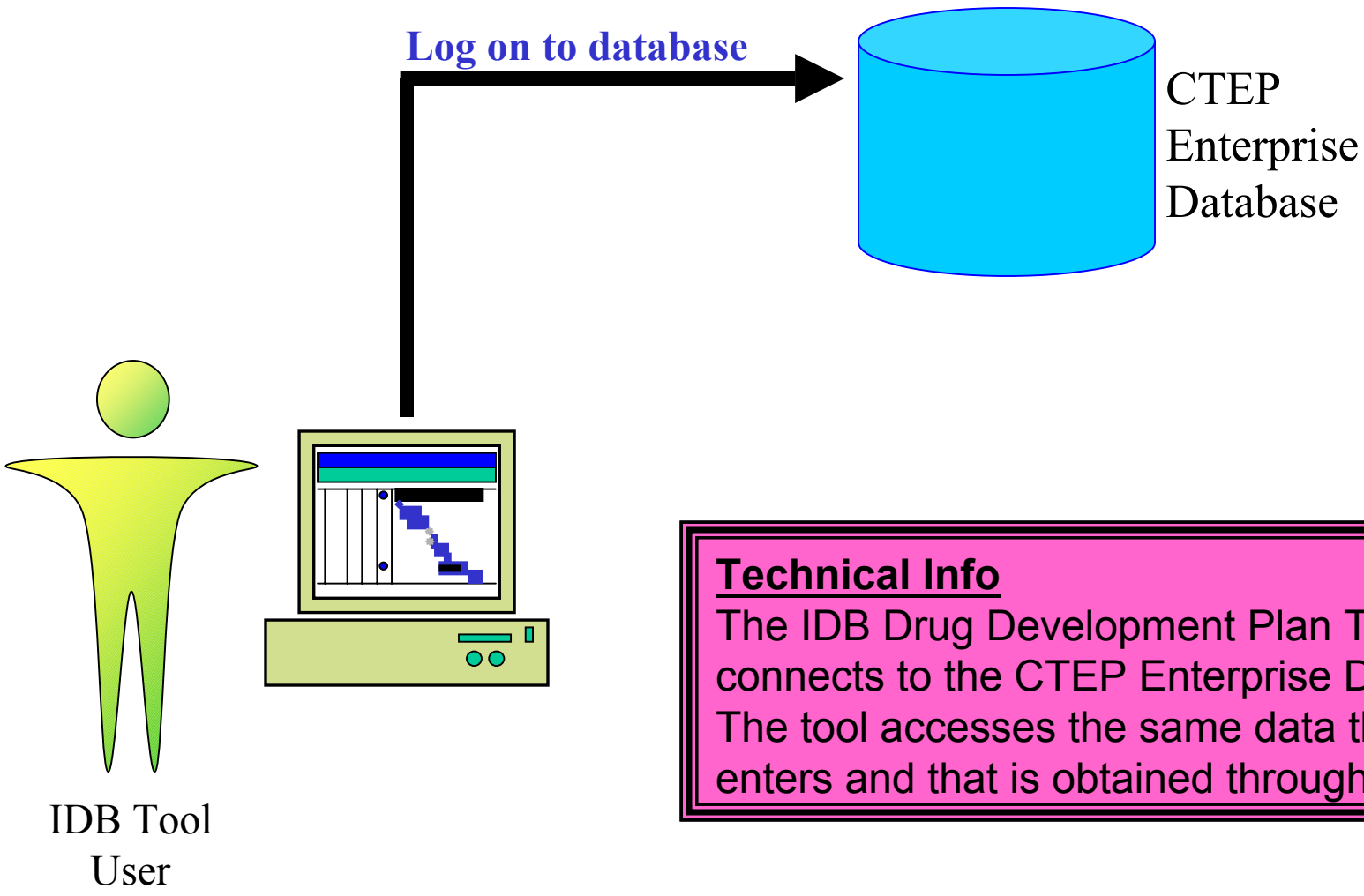
The CRS logs into the IDB Drug Development Plan using her/his own id and password. This is the same ID and password used to access any CTEP-ESYS application.



Tool Use

*Once the MS Project file opens, the User Login dialog box will appear. You may type in your **User Name** and **Password** to access the database. Then click **OK** or press the Enter key. Please note that if you click **Cancel**, you will not be able to use the IDB Drug Development Plan until you exit MS Project and then restart the application.*

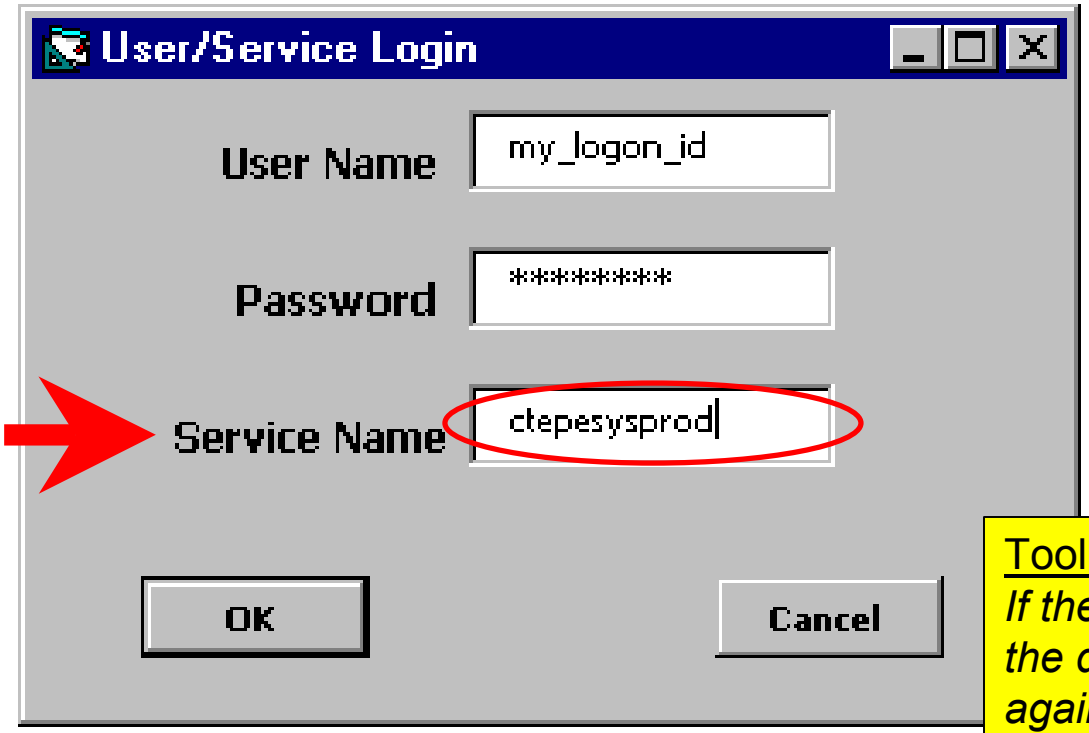
Logging on to the Database



Technical Info

The IDB Drug Development Plan Tool connects to the CTEP Enterprise Database. The tool accesses the same data that PIO enters and that is obtained through CDUS.

Logging on to the Database



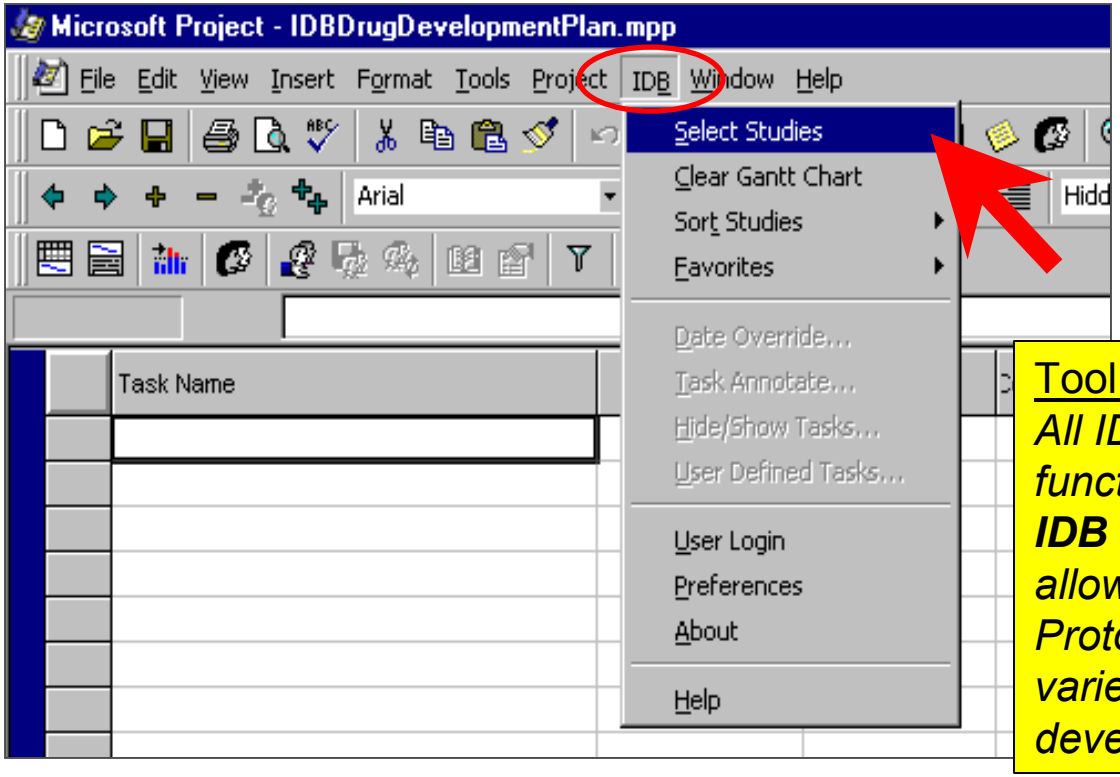
Tool Use

If the user makes a mistake logging on to the database, she or he will be asked to try again at the User/Service Login dialog box. For this type of login, the user must enter the Service Name along with the ID and password. The Service Name for the CTEP-ESYS database is **ctepesysprod**. *That stands for CTEP-ESYS Production.*

Starting a Search for a Study

Scenario Element:

The CRS decides to use the IDB Tool to find study T97-0118.
The CRS uses the *Select Studies* command on the IDB menu.



Tool Use

*All IDB Drug Development Plan functions may be accessed from the **IDB** Menu. The Select Studies option allows the user to search for clinical trial Protocols and Letters of Intent by a variety of means to use in the development of Gantt Charts*

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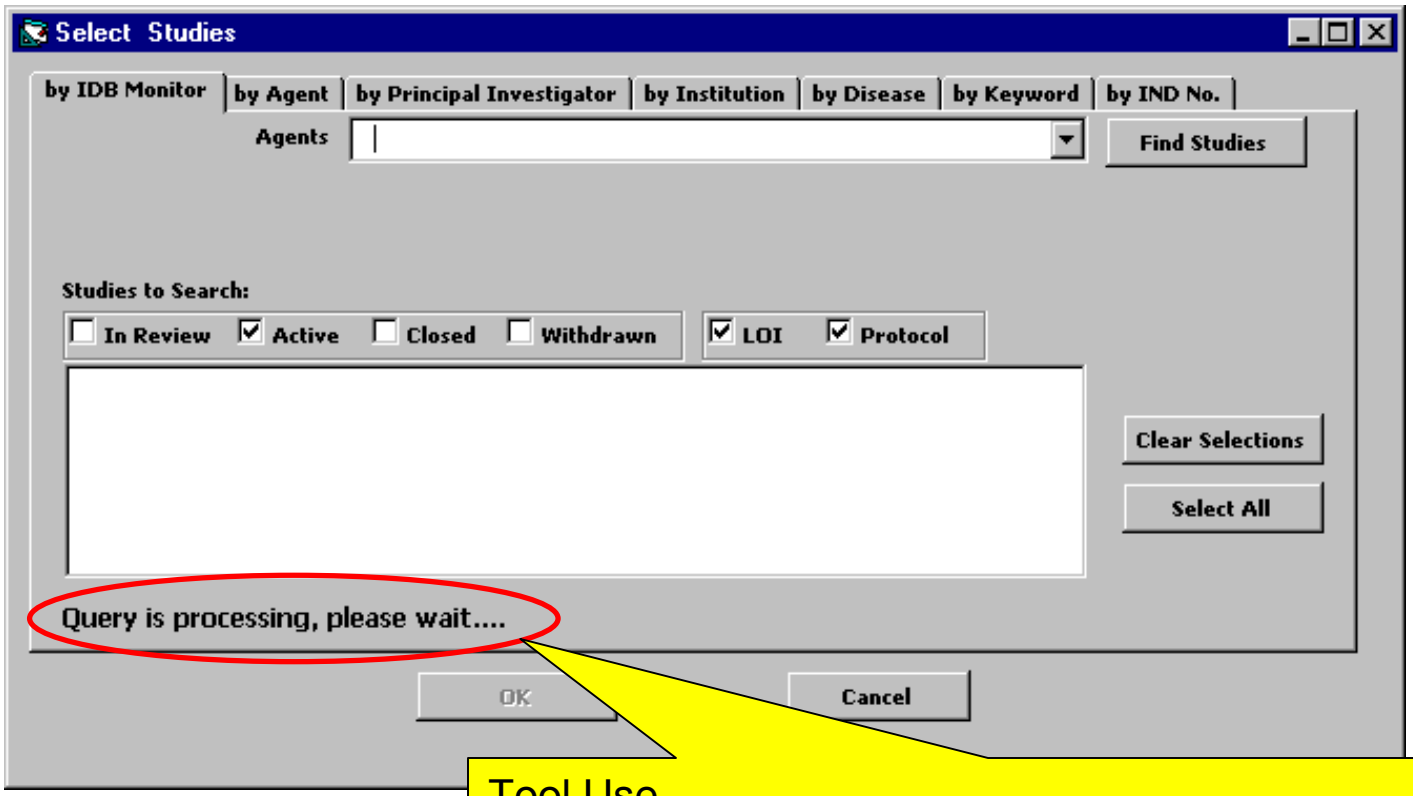
Starting a Search for a Study



Tool Use

*When the **Select Studies** command is used, the Select Studies dialog box opens. There may be a brief delay while information is queried from the database. During this delay, the message "Query is processing, please wait…" will appear in the message area near the bottom of the dialog box.*

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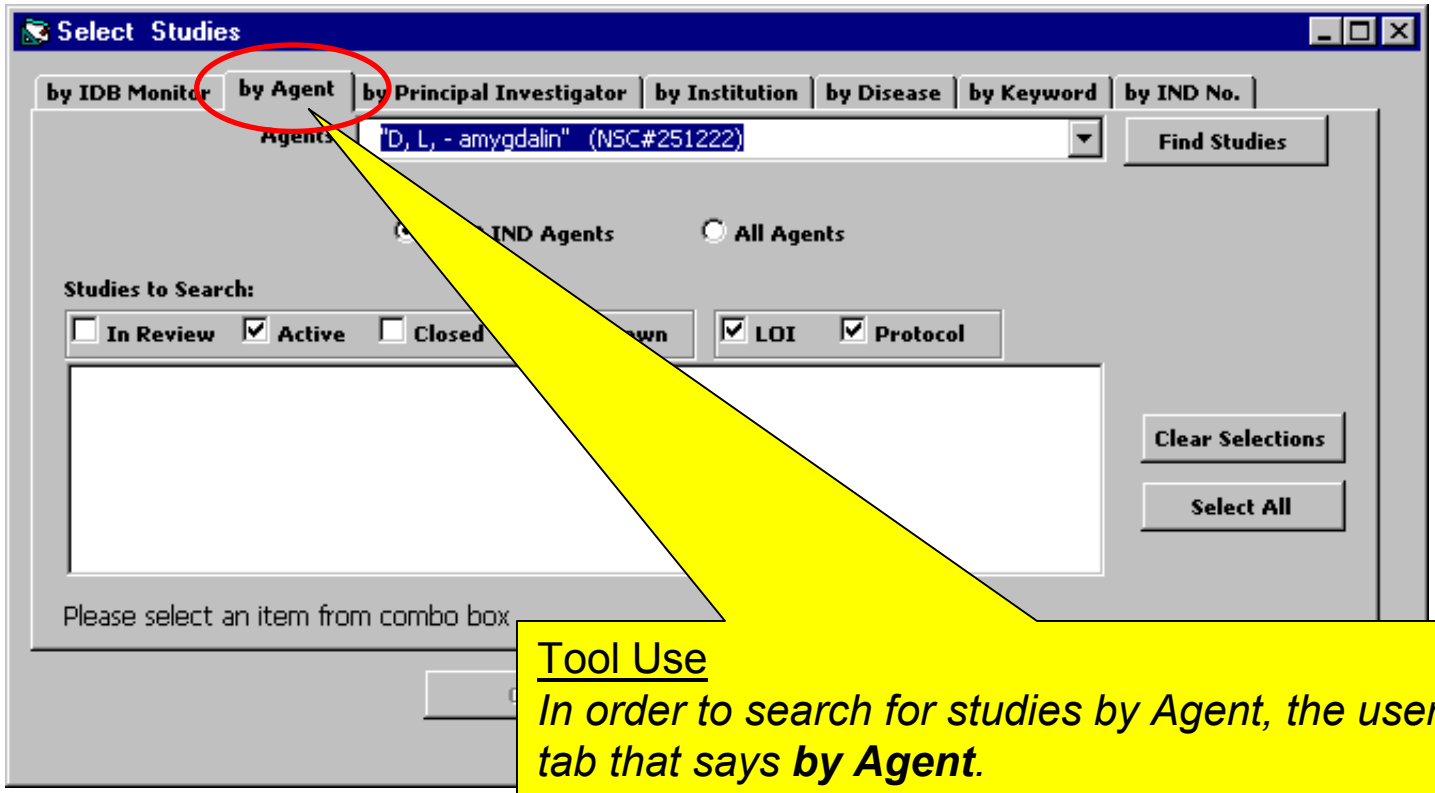
Searching for a Study by Agent

Scenario Element:

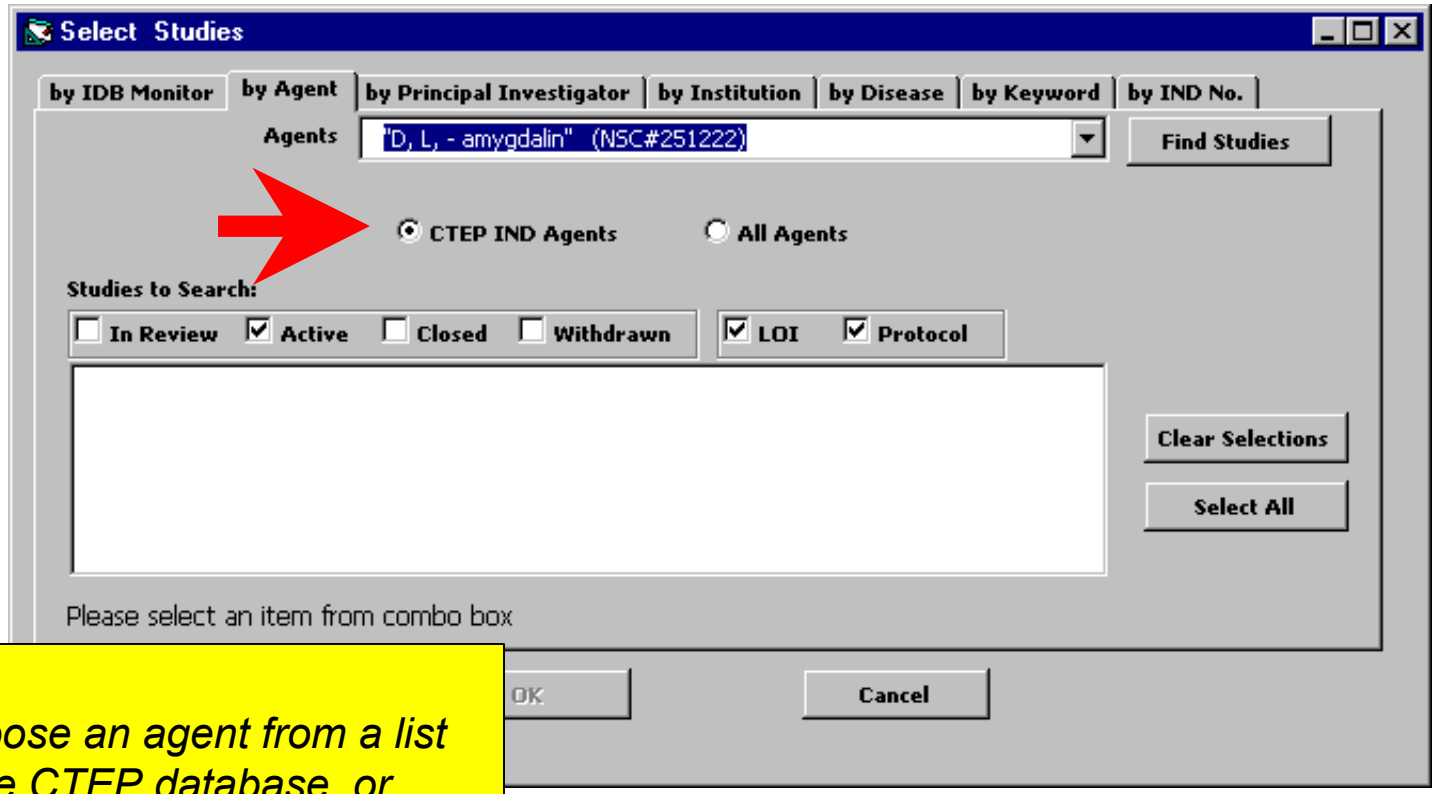
Since the CRS decides to search for the study in question by using its Agent, Cisplatin.



Tool Use

*In order to search for studies by Agent, the user clicks on the tab that says **by Agent**.*

Searching for a Study by Agent



Tool Use

The user may choose an agent from a list of All Agents in the CTEP database, or from a list of only Agents for which CTEP owns the IND. The user makes this selection by clicking on the appropriate radio button.

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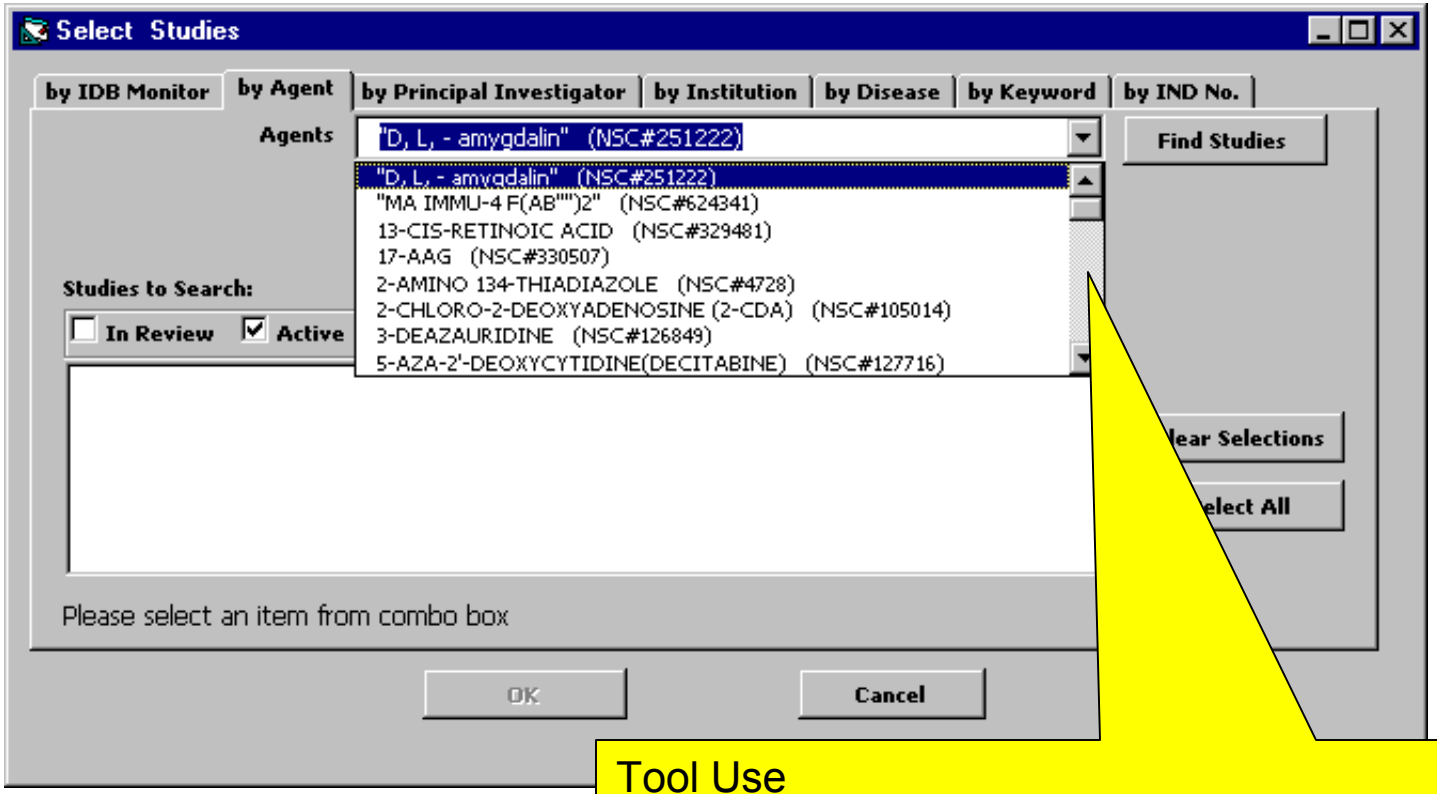
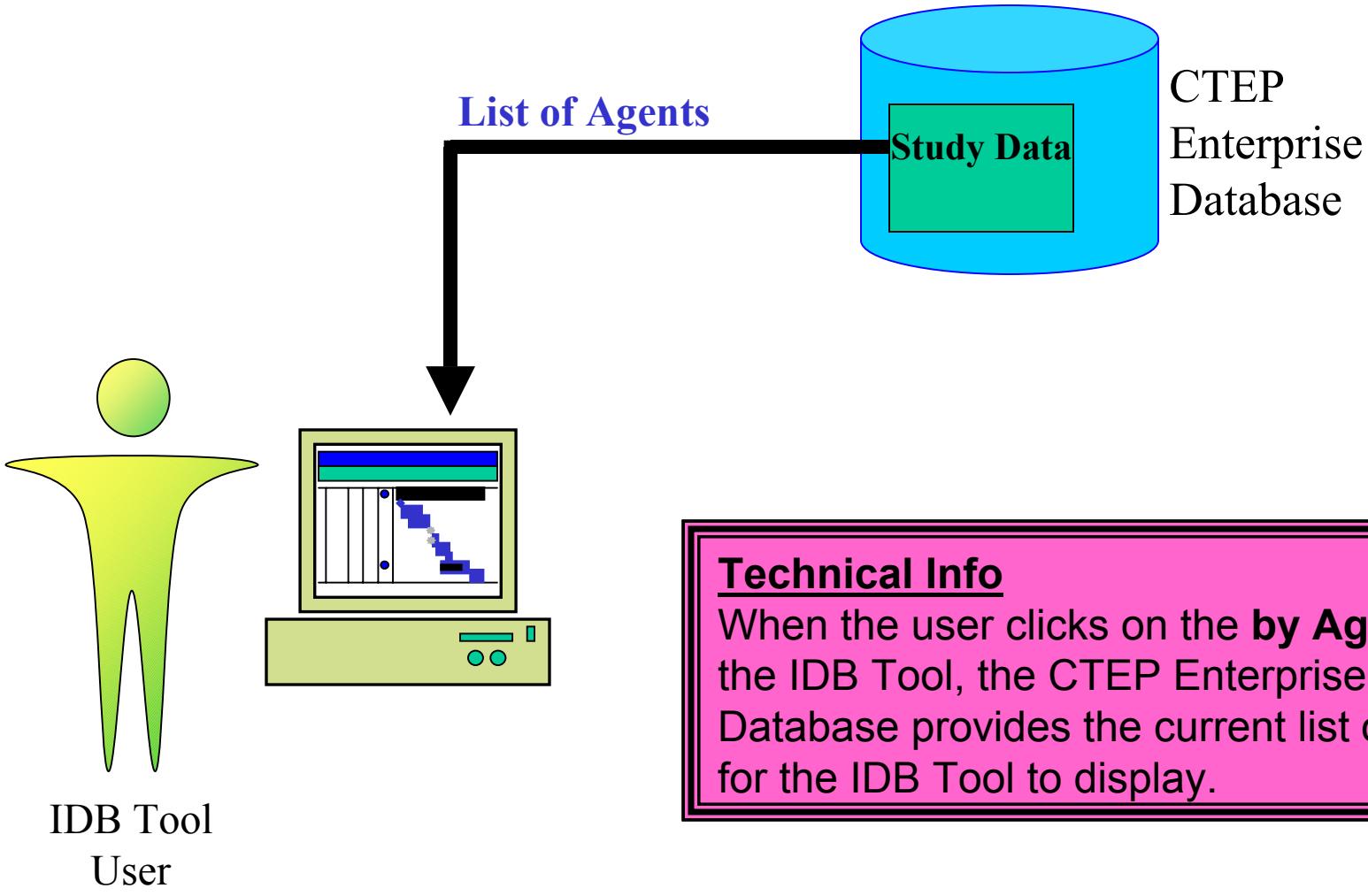
Searching for a Study by Agent



Tool Use

The drop-down list shows all the Agents that the user may select from in order to find a study. The user may move through the list using the mouse, or may use the page up, page down and arrow keys.

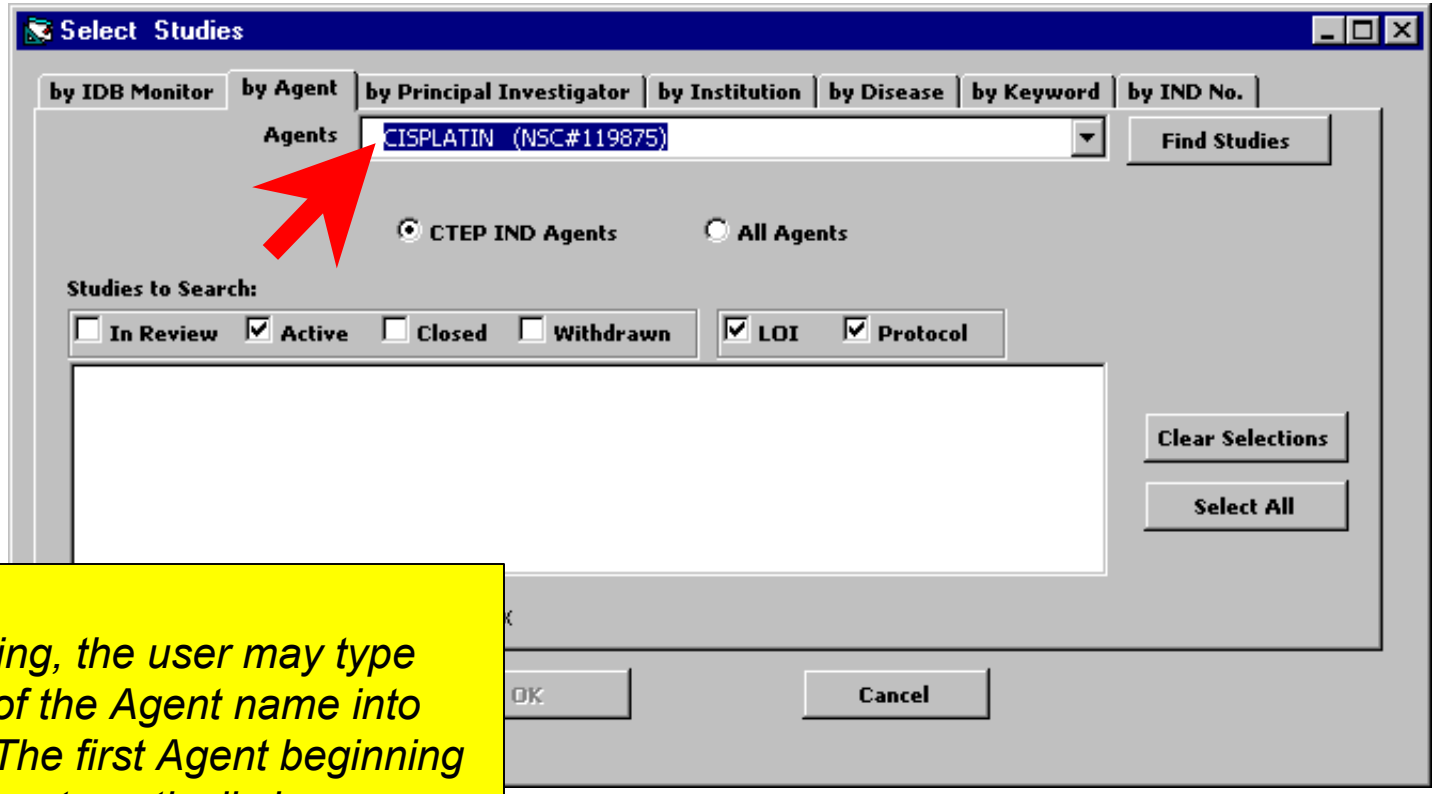
Searching for a Study by Agent



Technical Info

When the user clicks on the **by Agent** tab in the IDB Tool, the CTEP Enterprise Database provides the current list of Agents for the IDB Tool to display.

Searching for a Study by Agent



Tool Use

*Rather than scrolling, the user may type the the first letter of the Agent name into the **Agents** field. The first Agent beginning with that letter will automatically be highlighted. The user may then scroll from that point to find the Agent he or she wants.*

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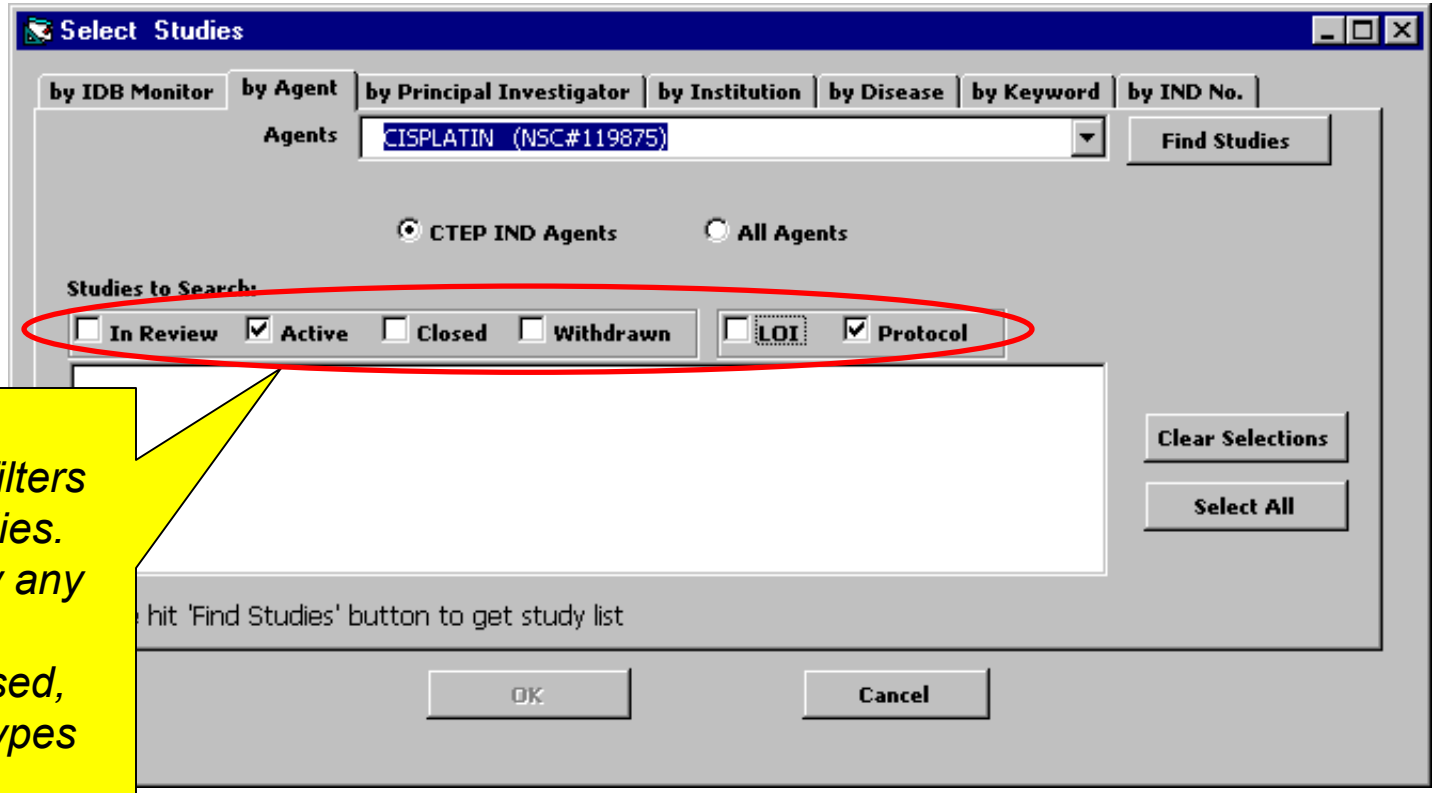
Searching for a Study by Agent

Scenario Element:

The CRS has set the search criteria to find all Active Protocols for Cisplatin.



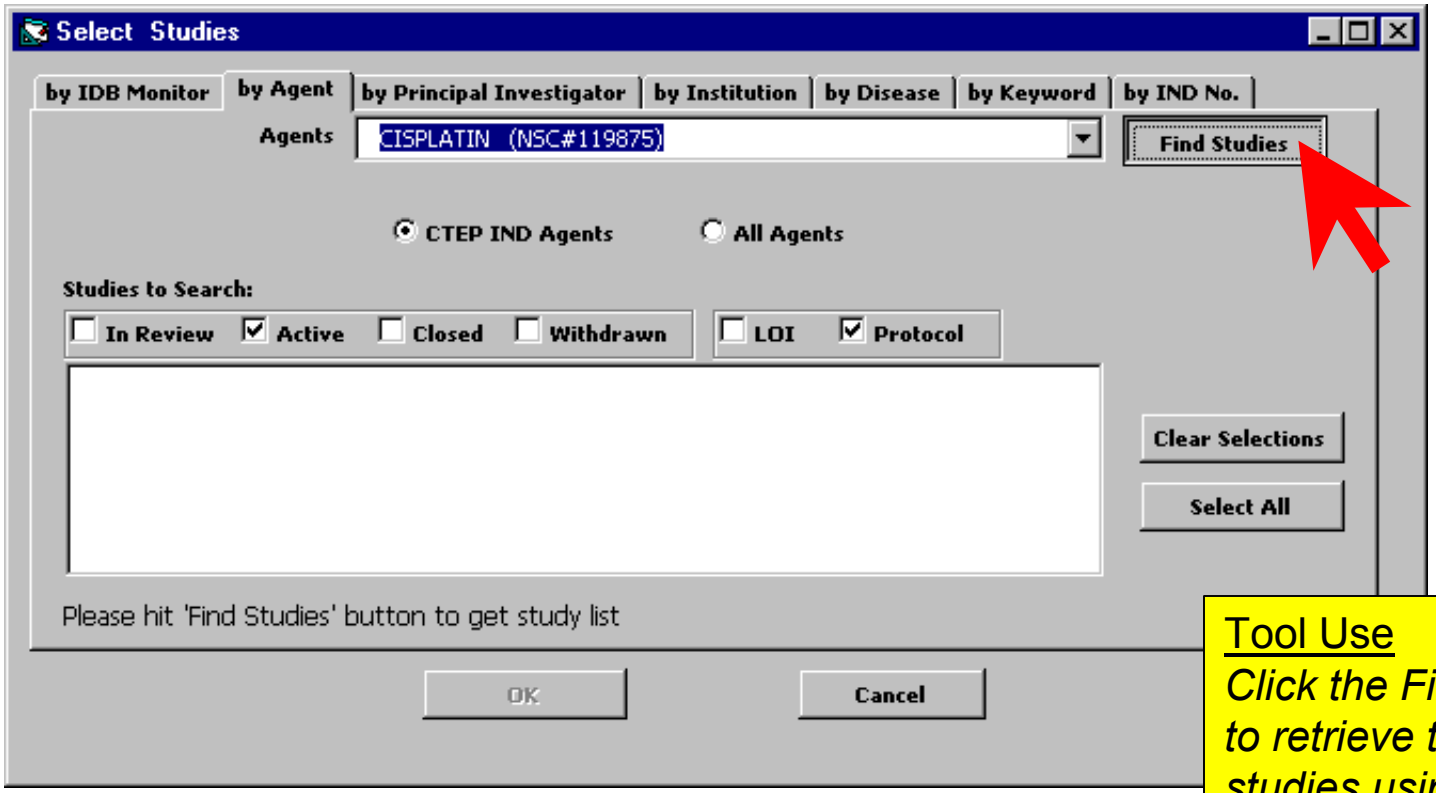
Tool Use

The user may apply filters to the search for studies. The user may specify any combination of study statuses (Active, Closed, etc.) and document types (LOI or Protocol).

Searching for a Study by Agent

Scenario Element:

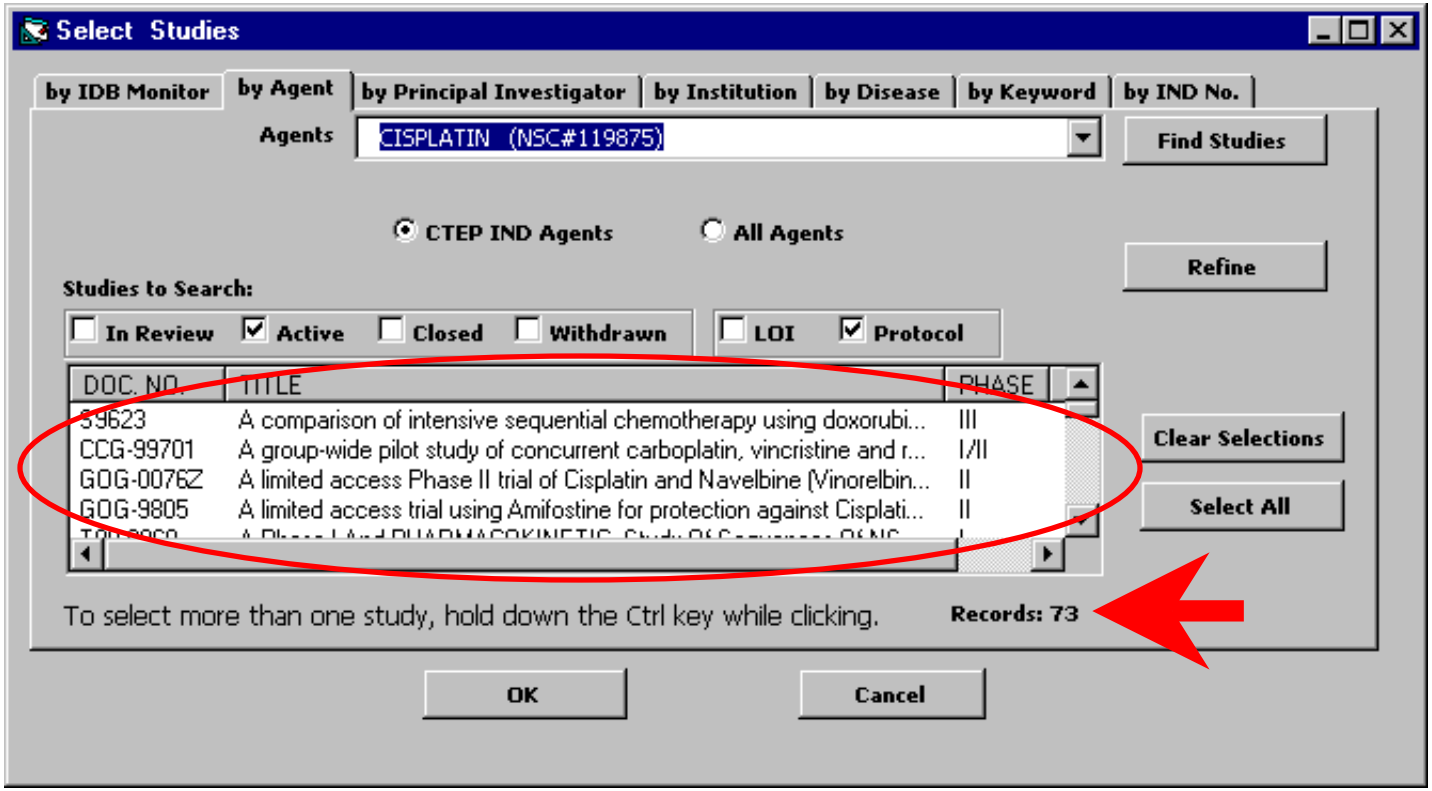
The CRS clicks the Find Studies button to find all the Active Protocols for Cisplatin.



Tool Use

Click the Find Studies button to retrieve the complete list of studies using this Agent.

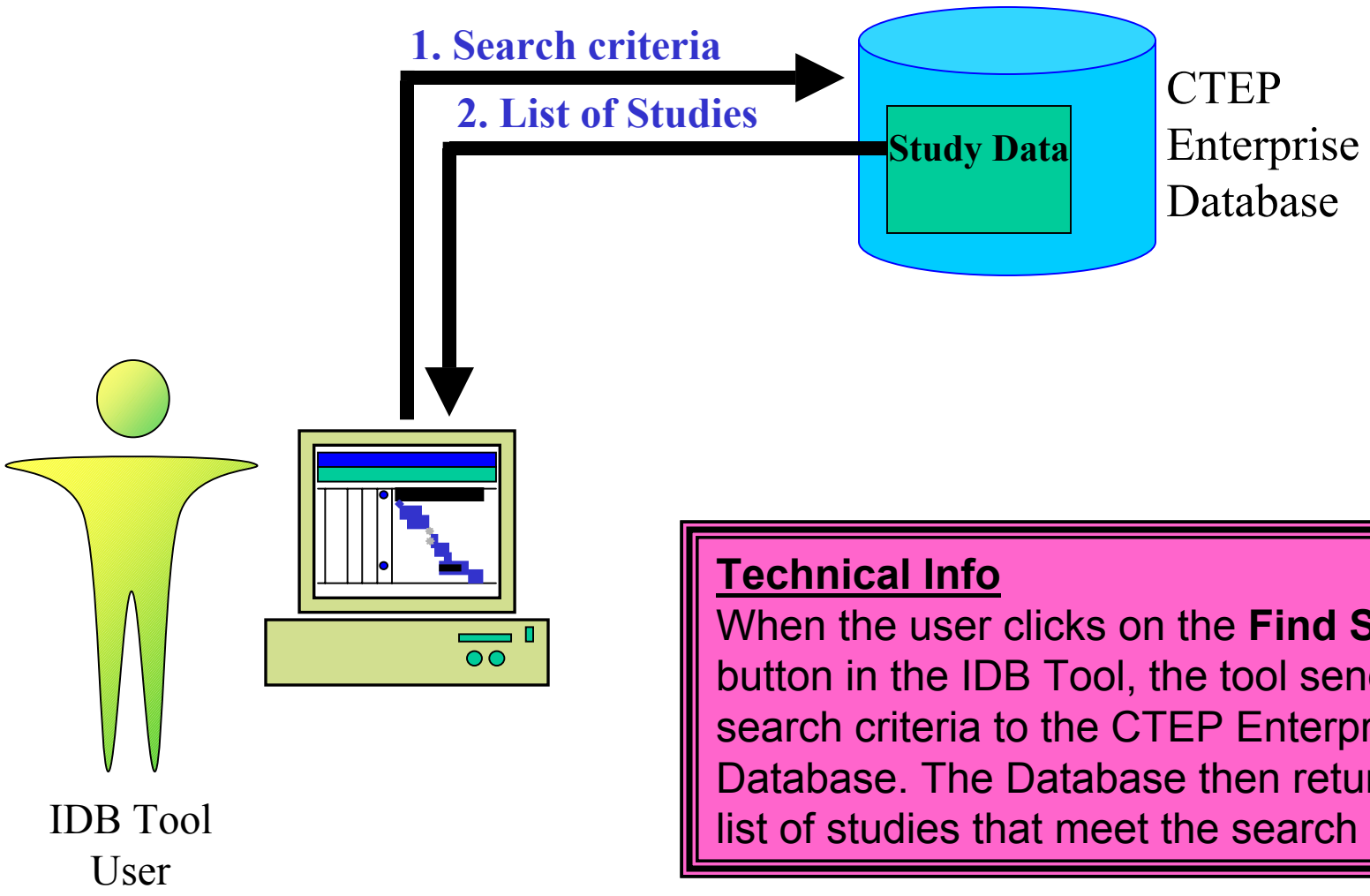
Searching for a Study by Agent



Tool Use

A list of all currently active studies using the Agent Cisplatin appears in the Document Window. The number of studies found appears below the Document Window.

Searching for a Study by Agent



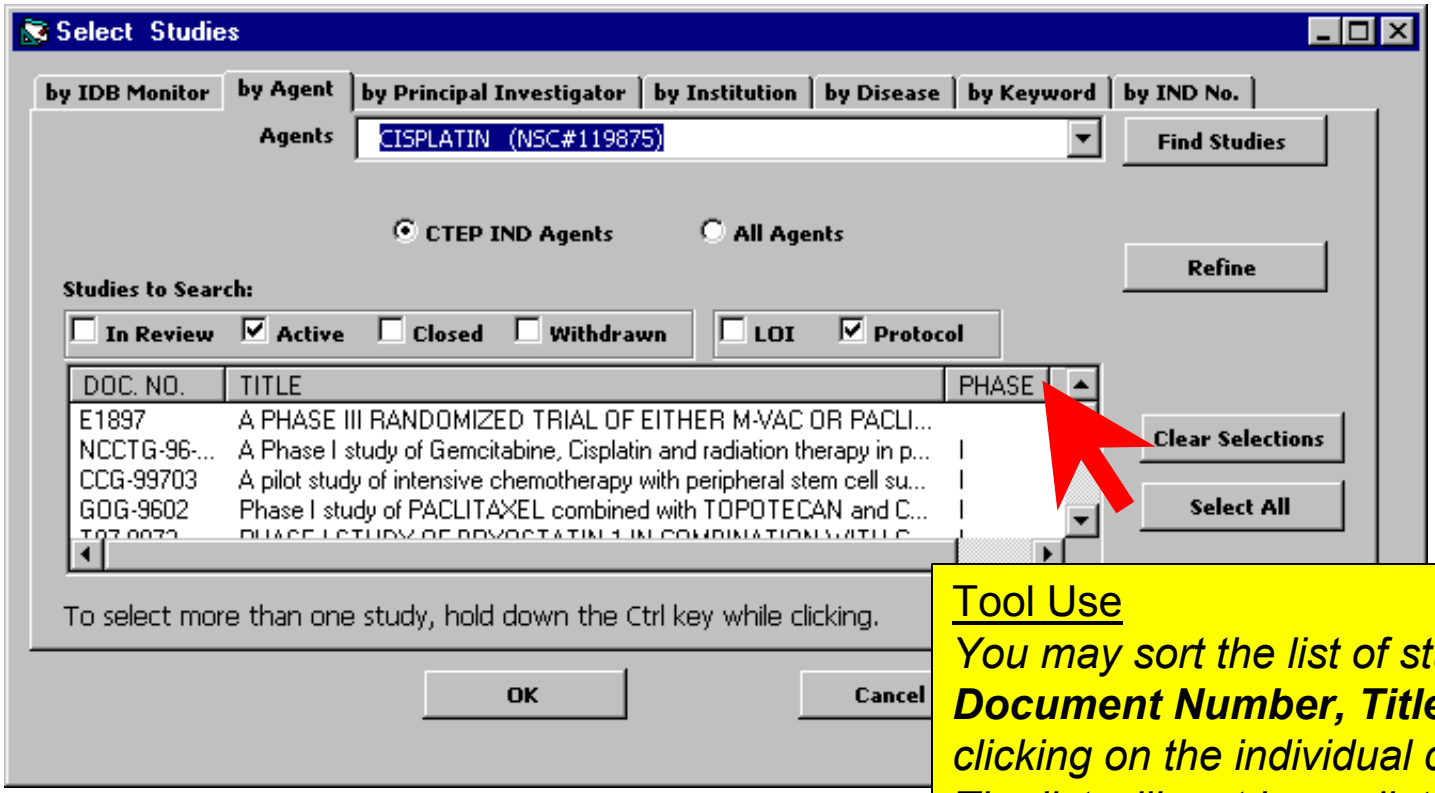
Technical Info

When the user clicks on the **Find Studies** button in the IDB Tool, the tool sends the search criteria to the CTEP Enterprise Database. The Database then returns the list of studies that meet the search criteria.

Sorting the List of Studies

Scenario Element:

The CRS knows that T97-0118 is a phase I study, so she clicks on the "Phase" heading to sort the study list by phase.



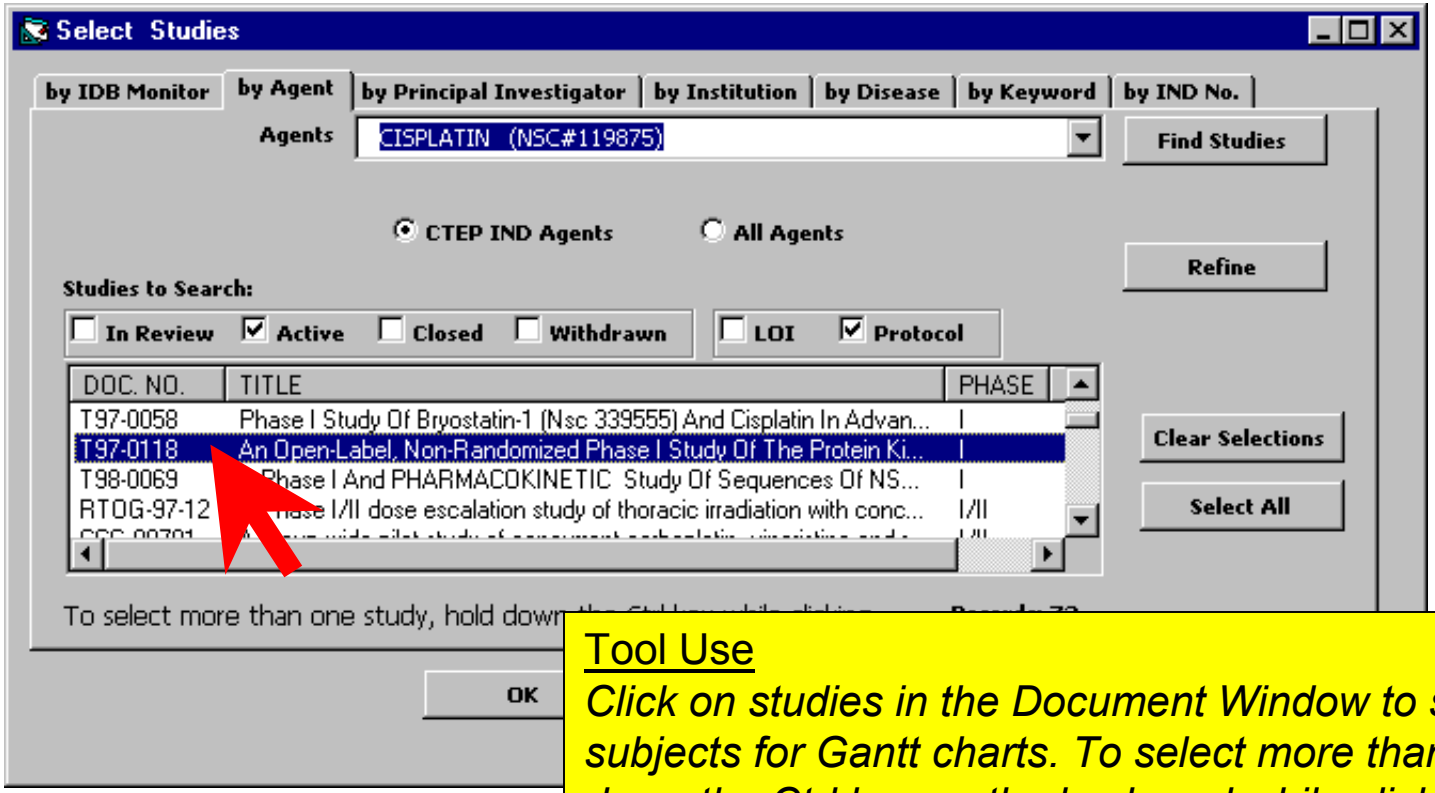
Tool Use

*You may sort the list of studies by **Document Number, Title,** or **Phase** by clicking on the individual column heading. The list will sort immediately.*

Selecting a Study to Chart

Scenario Element:

The CRS finds study T97-0118 in the list among the phase I studies. She clicks on T97-0118 to highlight it.



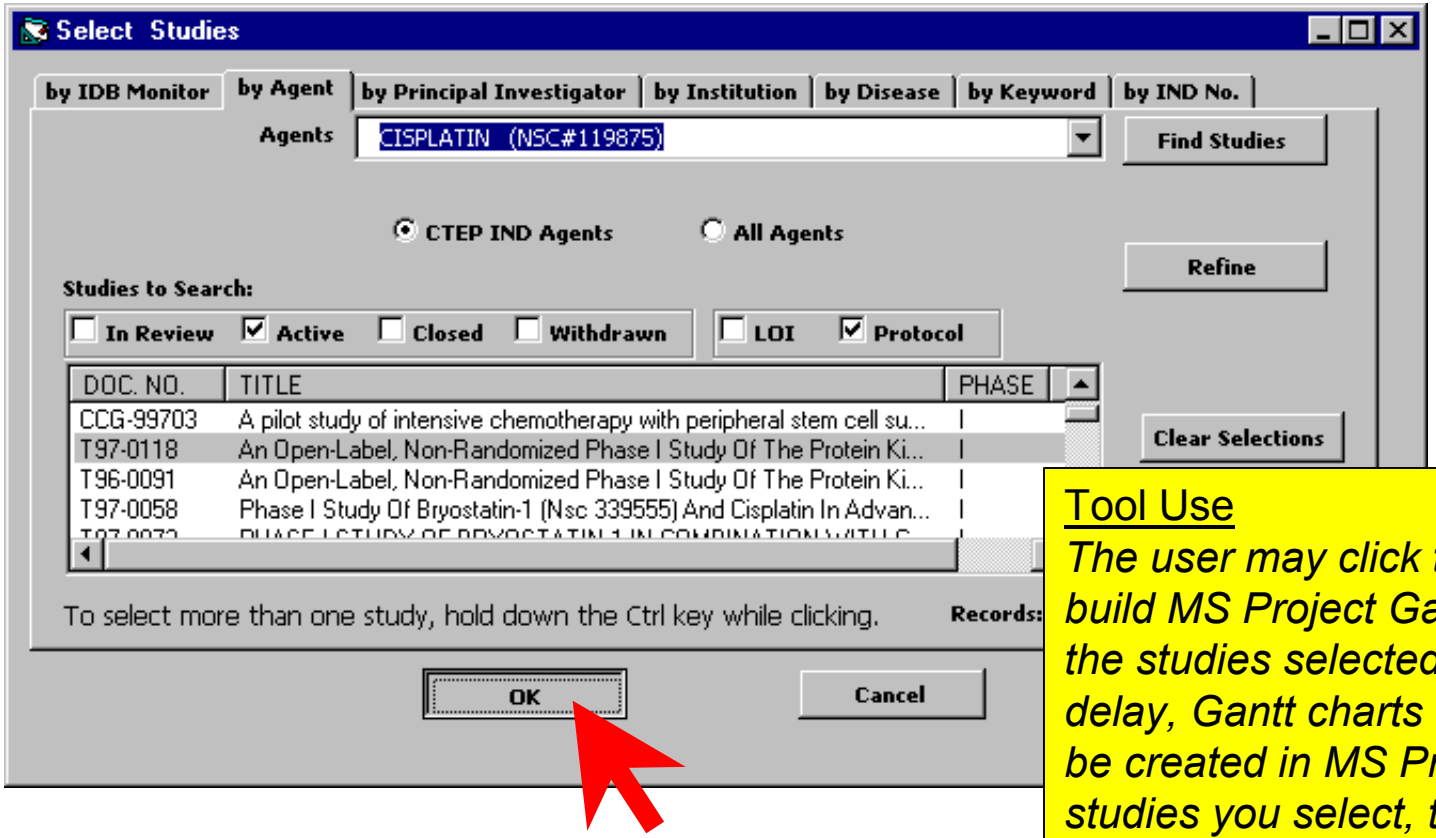
Tool Use

Click on studies in the Document Window to select them as subjects for Gantt charts. To select more than one study, hold down the Ctrl key on the keyboard while clicking on studies.

Creating a Gantt Chart

Scenario Element:

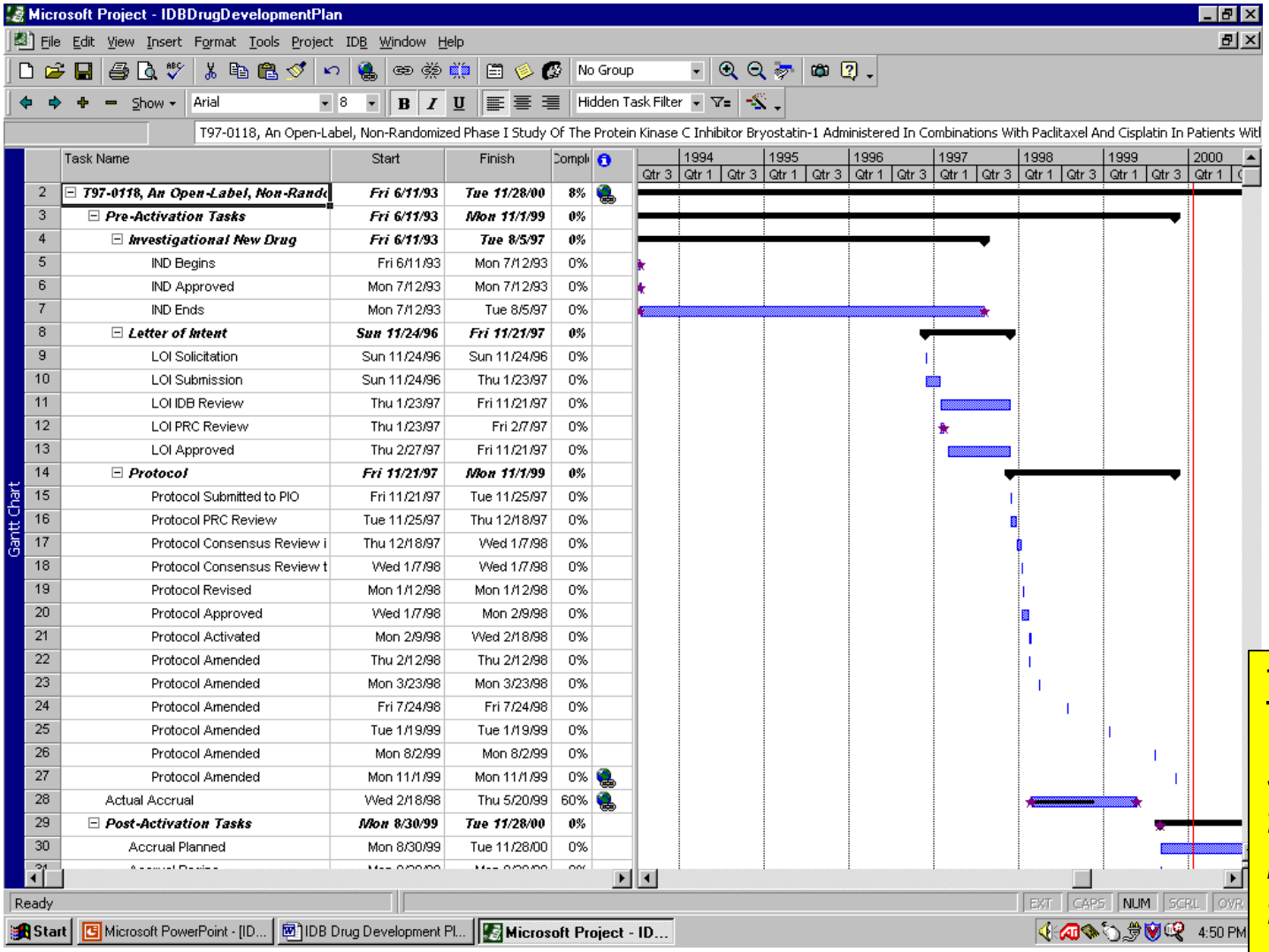
The CRS creates a Gantt Chart of the study by clicking the OK button.



Tool Use

*The user may click the **OK** button to build MS Project Gantt charts for all of the studies selected. After a brief delay, Gantt charts for the studies will be created in MS Project. The more studies you select, the longer the delay.*

Creating a Gantt Chart



Tool Use

The tool displays specified milestones for the selected study in a Gantt chart format.

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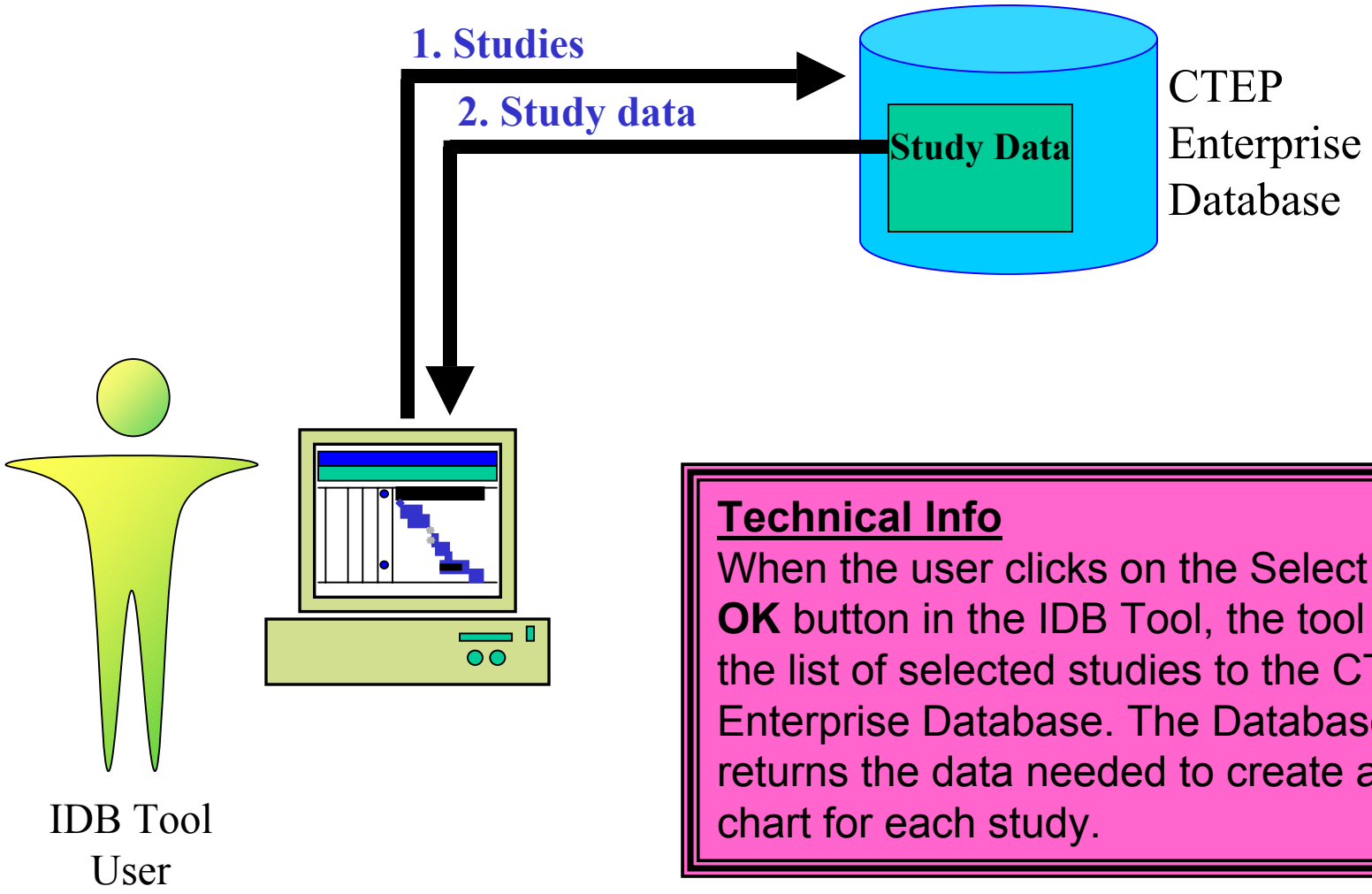
Creating a Gantt Chart



Technical Info

When the user clicks on the Select Studies **OK** button in the IDB Tool, the tool sends the list of selected studies to the CTEP Enterprise Database. The Database then returns the data needed to create a Gantt chart for each study.

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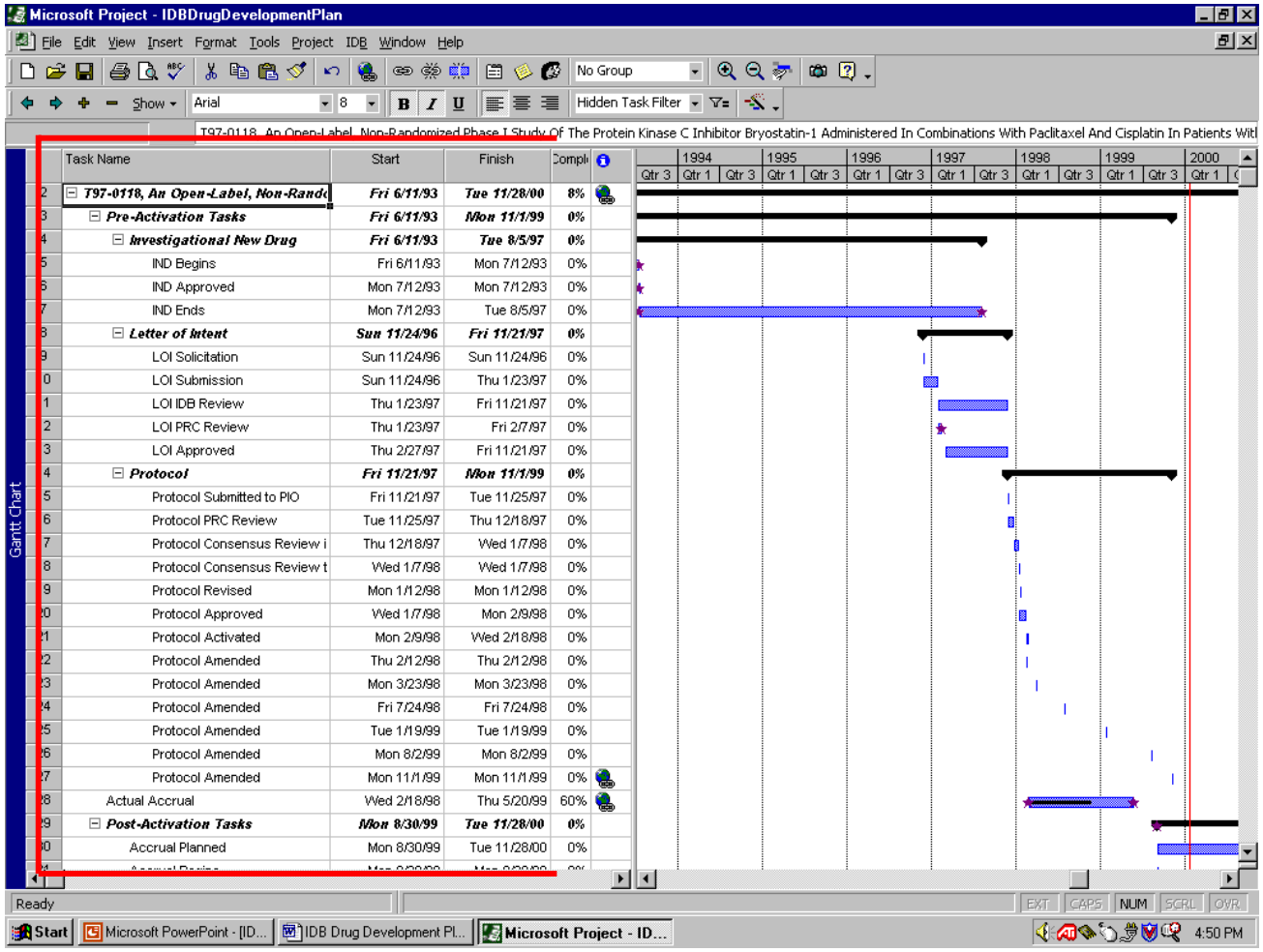
Viewing the Gantt Chart

Reading a Gantt Chart



Tool Use

The left side of the Gantt chart shows the milestones and tasks within the study. It also shows the start and finish dates for each milestone.

Scenario Element:

The CRS now views the Gantt Chart of study T97-0118.

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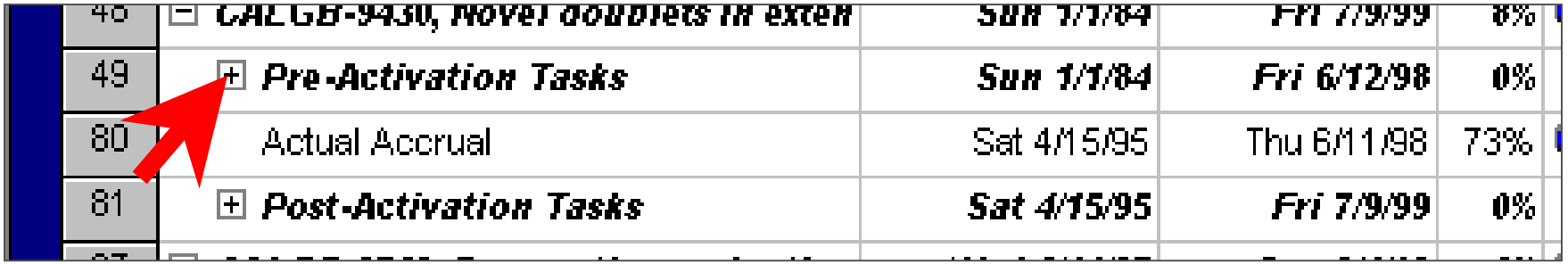
Reading a Gantt Chart



48	CALGB-9430, Novel doublets in exten	Sun 7/1/84	Fri 7/9/99	8%
49	**Pre-Activation Tasks**	**Sun 1/1/84**	**Fri 6/12/98**	**0%**
80	Actual Accrual	Sat 4/15/95	Thu 6/11/98	73%
81	**Post-Activation Tasks**	**Sat 4/15/95**	**Fri 7/9/99**	**0%**

Tool Use

The tool displays each study's milestones and tasks in three main groups: Pre-Activation Tasks, Actual Accrual, and Post-Activation Tasks.

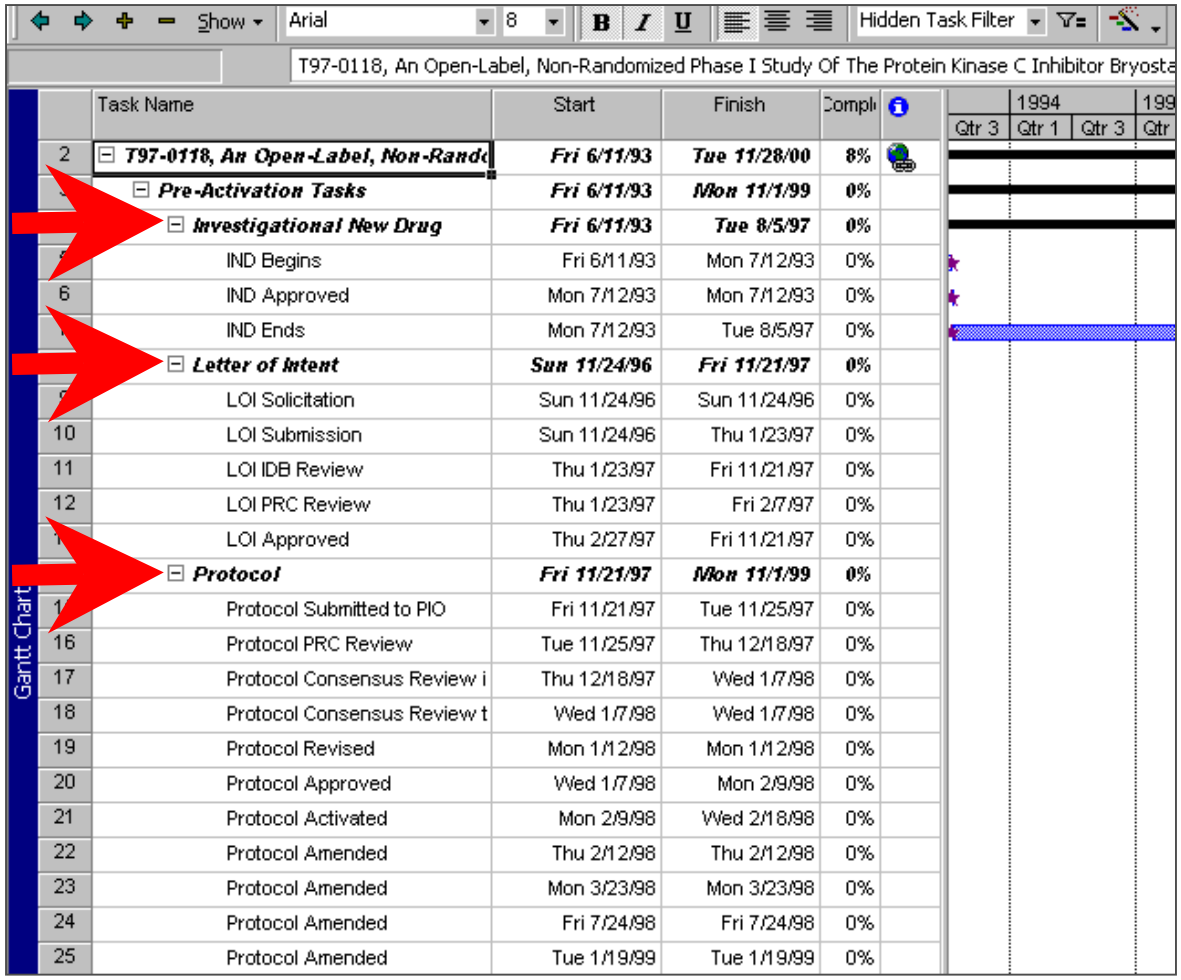
Tool Use

The use may open up or close a group of tasks by clicking on the plus sign or minus sign next to it. This will display all the tasks contained within that grouped or "rolled-up" task.

Reading a Gantt Chart

Tool Use

The Pre-Activation Tasks group contains three lower level groupings: Investigational New Drug, Letter of Intent, and Protocol. Each of these lower level groupings contains individual tasks and milestones that can be viewed or hidden by clicking on the plus or minus sign.



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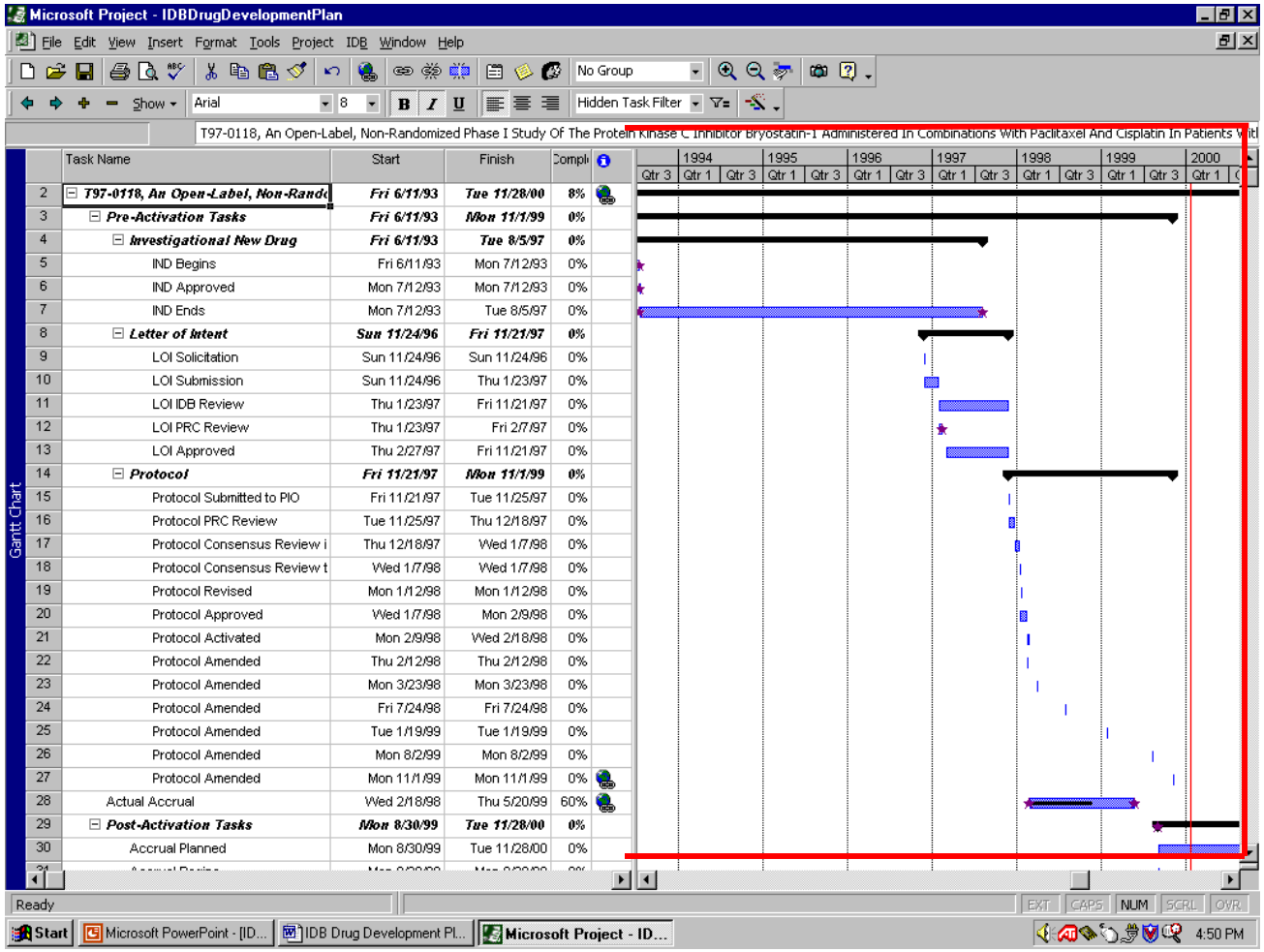
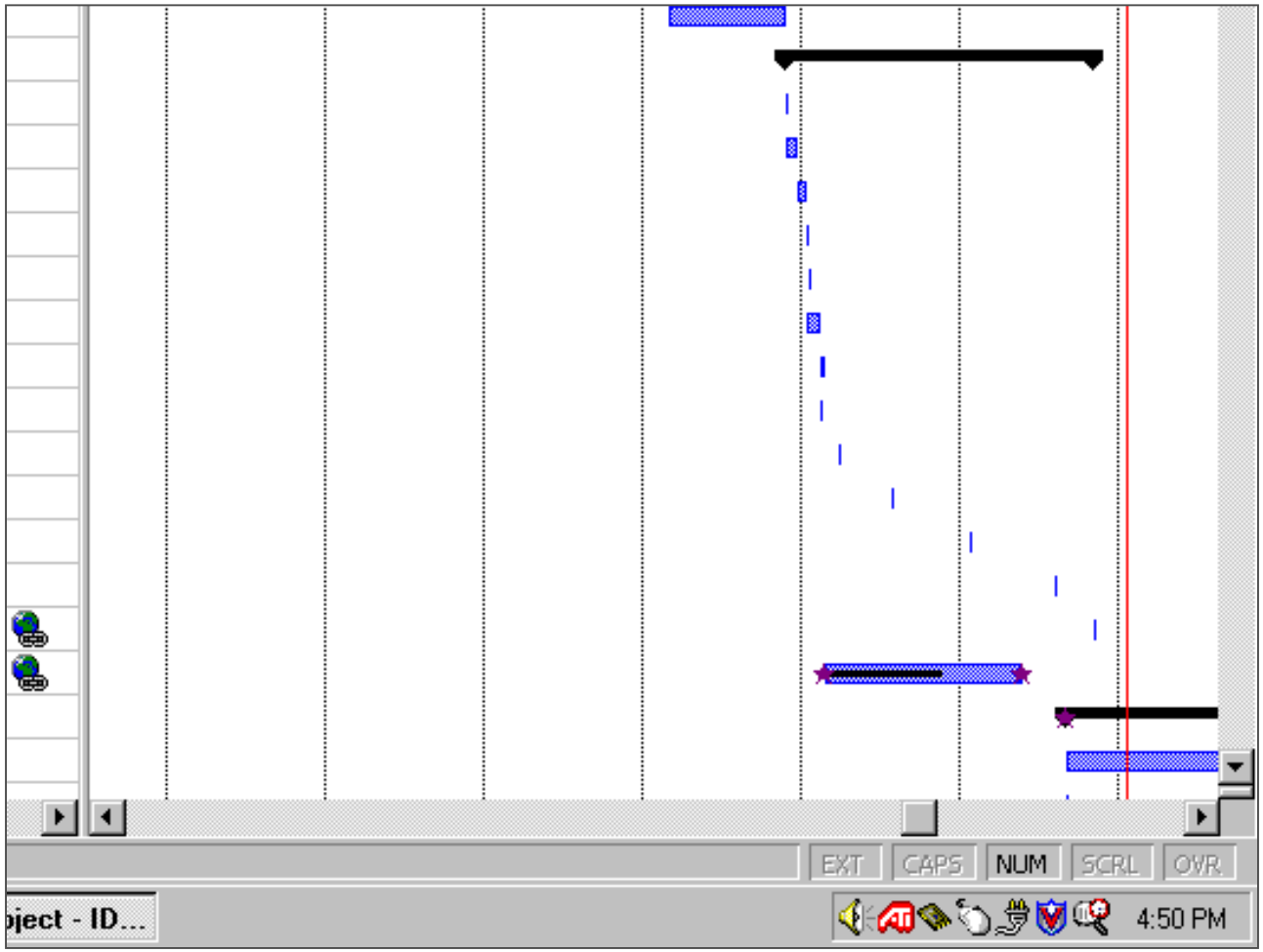
Reading a Gantt Chart



Tool Use

The right side of the Gantt chart shows the duration of each milestone or task. This is displayed by symbols and horizontal bars, with the timeline at the top.

Reading a Gantt Chart



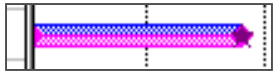
Tool Use

The bars and symbols on the IDB Drug Development Plan Tool Gantt chart are coded to convey specific meanings.

IDB Tool Gantt Chart Symbols

Blue Bar  This represents a task within a study (e.g., LOI Submitted, Protocol Approved).

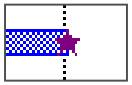
Black Bar with Black Diamond Ends  This represents a summary task within a study (e.g., Pre-Activation Tasks, Protocol).

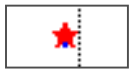
Pink Bar below Blue Bar  This represents a task with a start date and/or finish date prior to January 1, 1984. That is the earliest date that MS Project can display.

Brown Bar  This represents a task for which the database's start date is later than the database's finish date.

Black Line in a Blue Bar  This symbol is only used for the *Accrual Actual* task. The black line represents the percentage of the total desired accrual that was completed at the last accrual reporting date.

Diamond or Very Short Blue Bar   This is a task that takes place on a single day. For example, a Protocol Revision is approved on a specific date and would be represented by one of these symbols.

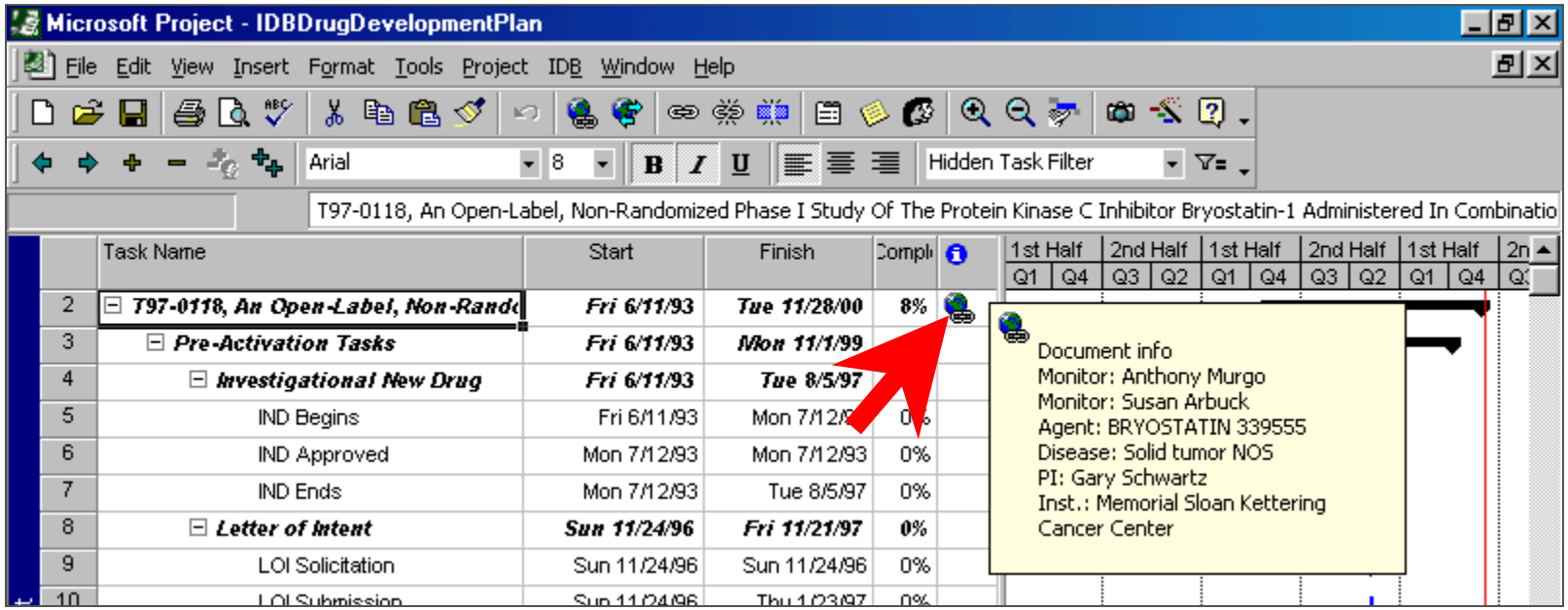
Pink/Purple Star  This represents a start date or a finish date that is based on a projection. This is done in cases where no actual database value is available for the date, so a projection from another known date is substituted. This symbol will usually appear at the end of a blue bar, or on top of a very short blue bar.

Red Star  This represents a date that has been overridden by a user. This may be done in cases where the user knows that a projected date or a database date is incorrect. This symbol will usually appear at the end of a blue bar, or on top of a very short blue bar.

Reading Notes in a Gantt Chart

Scenario Element:

The CRS reviews the study information pop-up, notes the IDB Monitors and sees that this study also involves the Agent Bryostatin.

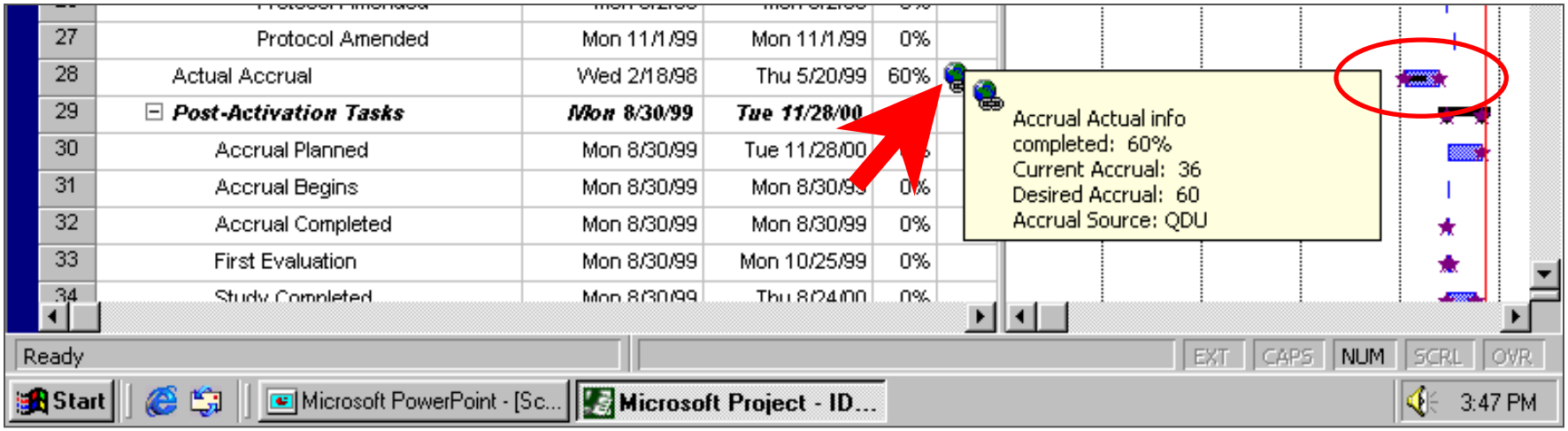


Tool Use

This symbol indicates that a note of some kind is attached to the task. The user may read the note by placing the cursor over this symbol but not clicking the mouse. The note next to the study title contains general study information.

Reading Notes in a Gantt Chart

Scenario Element:
The CRS reviews the study's accrual information.



Tool Use

The note next to the Actual Accrual task contains accrual information, including the most recent source of accrual reporting. The bar next to this task contains a black progress bar that shows the percentage of planned accrual completed.

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Adding Notes and User-Defined Tasks to Gantt Charts

Annotating Tasks in a Gantt Chart

Scenario Element:

The CRS needs to add a note about patient responses to the Gantt chart for study T97-0118. This note will be seen by the IDB Monitor the next time he or she charts the study. The CRS decides to add the note to the "Accrual Begins" task in the Post-Activation Tasks section of the Gantt chart.

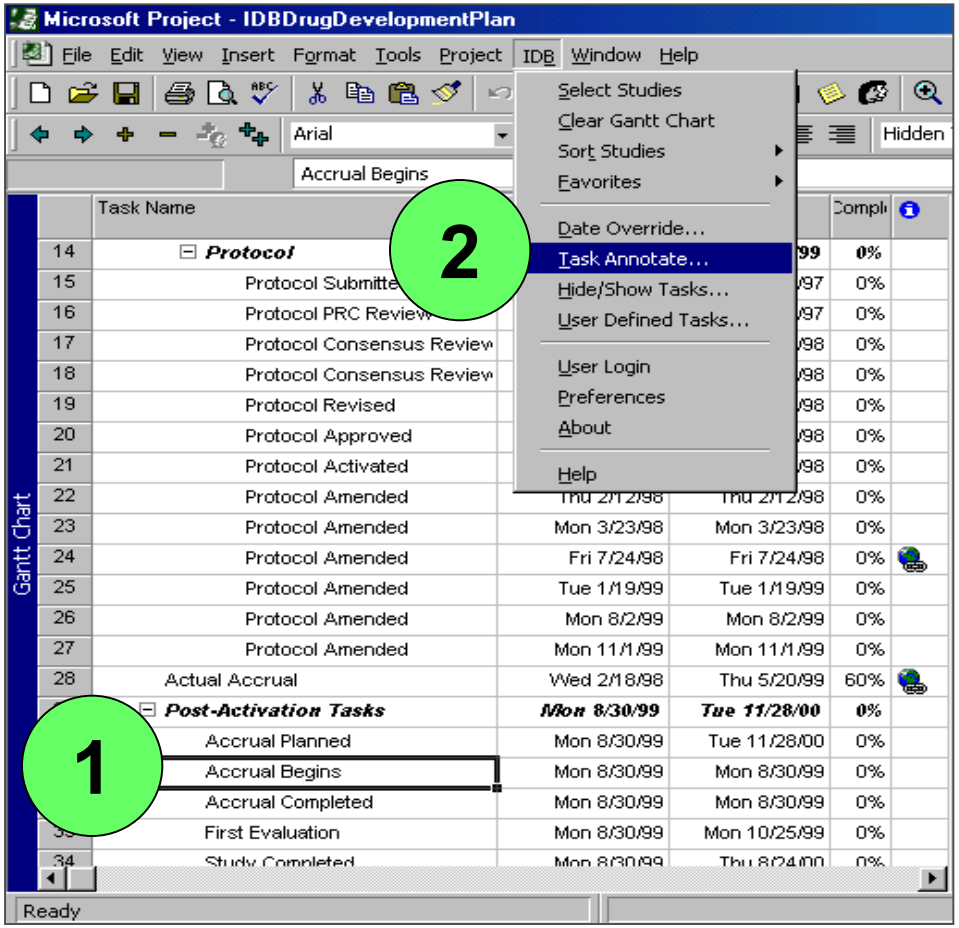
Annotating Tasks in a Gantt Chart

Scenario Element:

The CRS first selects the "Accrual Begins" cell in the Gantt Chart. Next, the CRS selects the Task Annotate command from the IDB menu.

Tool Use

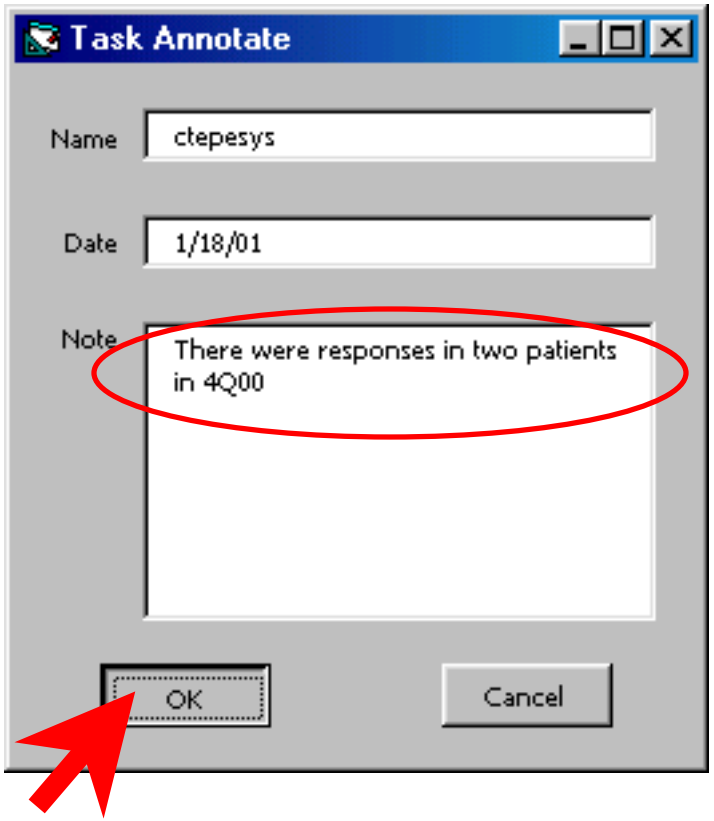
*The **Task Annotate** feature allows users to attach notes to any task displayed in the Gantt chart. The notes will be saved to a special table in the CTEP Enterprise Database and remain accessible to any other user who charts the study using the IDB Drug Development Plan. The system also records and displays the date and user name associated with the last annotation.*



Annotating Tasks in a Gantt Chart

Scenario Element:

When the Task Annotate dialog box appears, the CRS types "There were responses in two patients in 4Q00" and clicks OK.

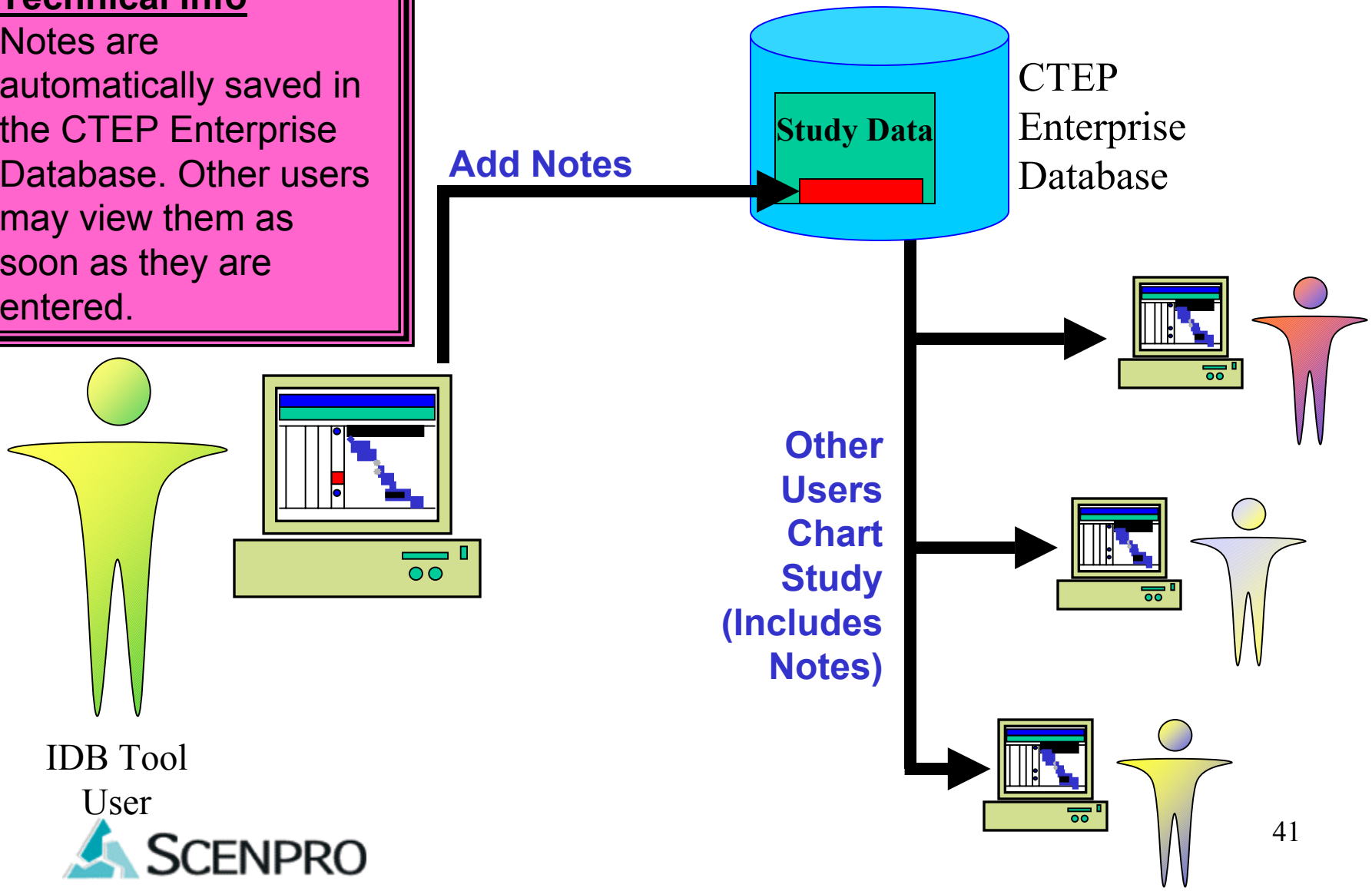


Tool Use

*The **Task Annotate** dialog box allows the user to enter a short note of up to 255 characters in the CTEP Enterprise Database. The note will be accessible by any user who charts the study. The user need not fill out the Name and Date fields in this dialog box. They are populated with the user's ID and the current date.*

Annotating Tasks in a Gantt Chart

Technical Info
Notes are automatically saved in the CTEP Enterprise Database. Other users may view them as soon as they are entered.



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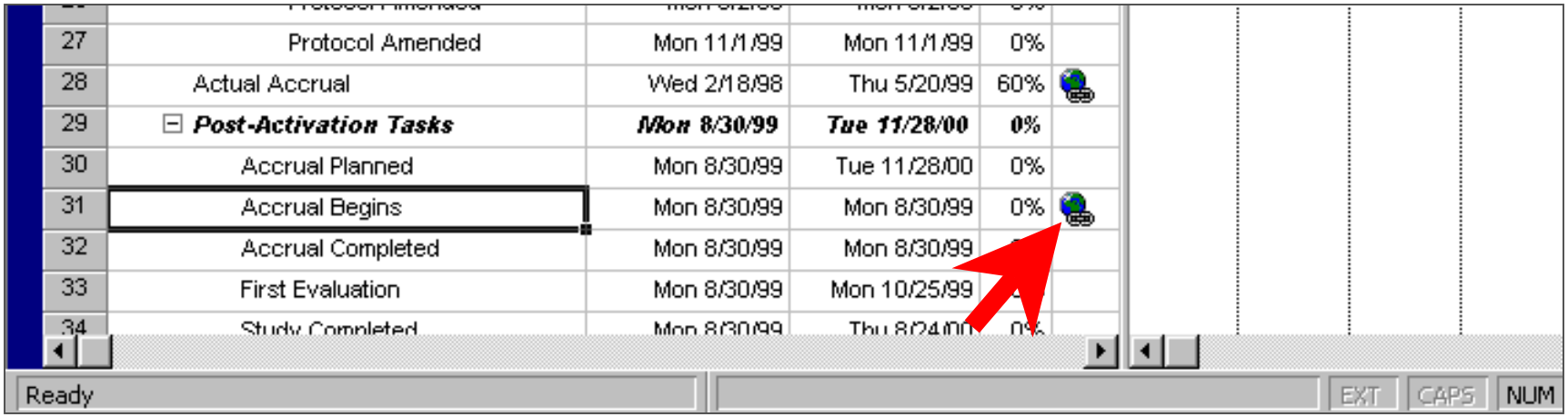
Annotating Tasks in a Gantt Chart

Scenario Element:

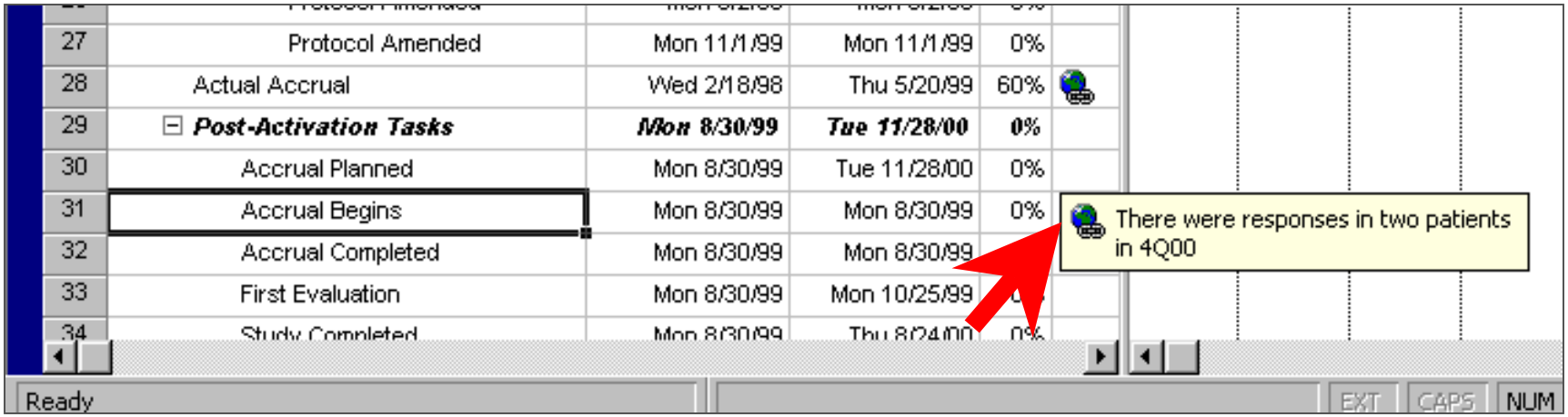
The CRS verifies that a note symbol now appears next to the "Accrual Begins" task in the Gantt Chart.



Annotating Tasks in a Gantt Chart

Scenario Element:

The CRS reads the note by hovering the mouse over the icon.



Tool Use

*The user may view the note contents by hovering the mouse over the hyperlink symbol. This method displays the note text, but does not show the user name and date. If the user clicks on the hyperlink symbol, the following message will appear: "Cannot open the specified file." This is not an error, and the user may simply click the **OK** button to return to the Gantt chart.*

Adding User-Defined Tasks to a Gantt Chart

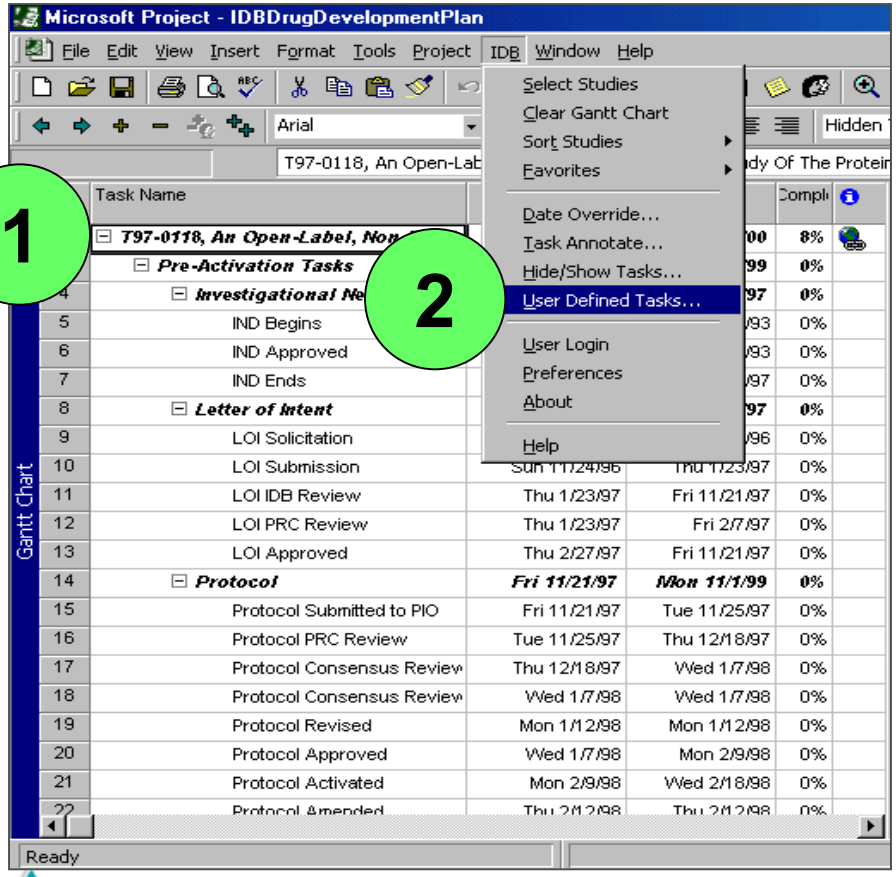
Scenario Element:

The CRS needs to add a user-defined task called "Solicit Phase II Study" to the Gantt chart for study T97-0118. This task will be seen by the IDB Monitor the next time he or she charts the study. The CRS decides to add the task after the "Actual Accrual" task in the Gantt chart.

Adding User-Defined Tasks to a Gantt Chart

Scenario Element:

The CRS first selects any task in study T97-0118. Then the CRS selects the "User Defined Tasks…" command from the IDB menu.



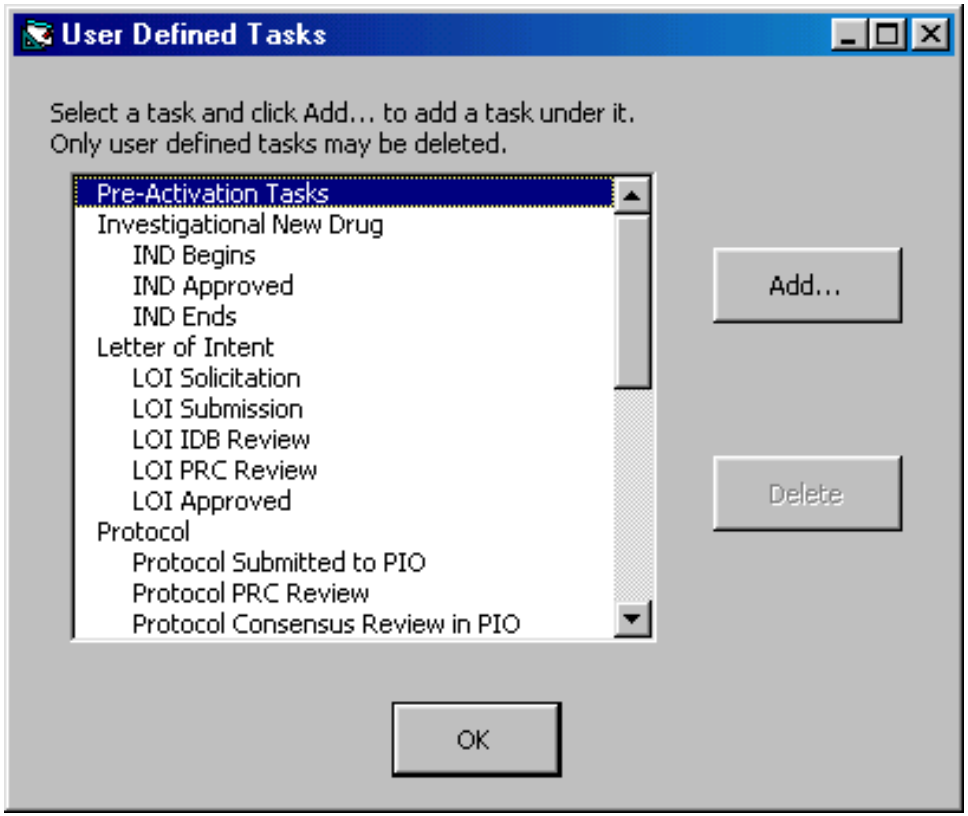
Tool Use

The user may define one or more tasks that are not normally part of a study. The tasks will be displayed as part of the study's Gantt chart whenever any user creates the chart.

*To create a User-Defined Task in a study, a Gantt chart of that study must currently be displayed on the screen. The user should click on the name of any task within the study and then click on the **User-Defined Tasks** option located on the **IDB** drop-down menu.*

SCENPRO

Adding User-Defined Tasks to a Gantt Chart



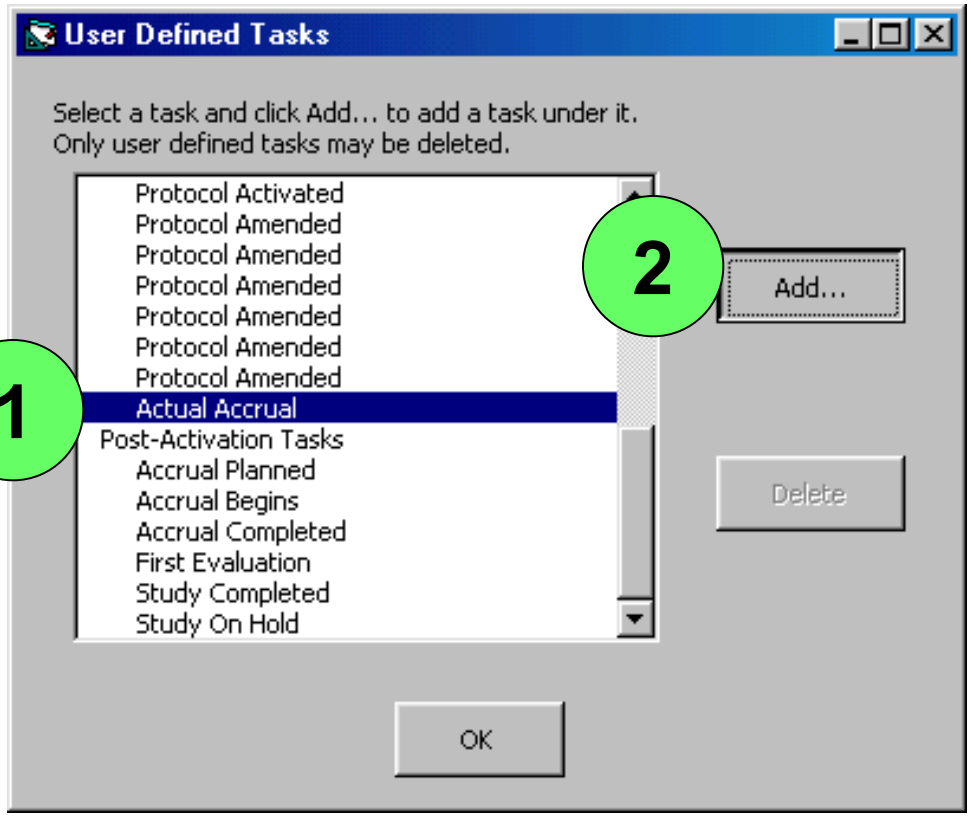
Tool Use

*The **User-Defined Tasks** dialog box contains a list of all the tasks in the study. The user may scroll down through the list to find the correct spot for the user-defined task.*

Adding User-Defined Tasks to a Gantt Chart

Scenario Element:

The CRS inserts a user-defined task below the existing Actual Accrual task.



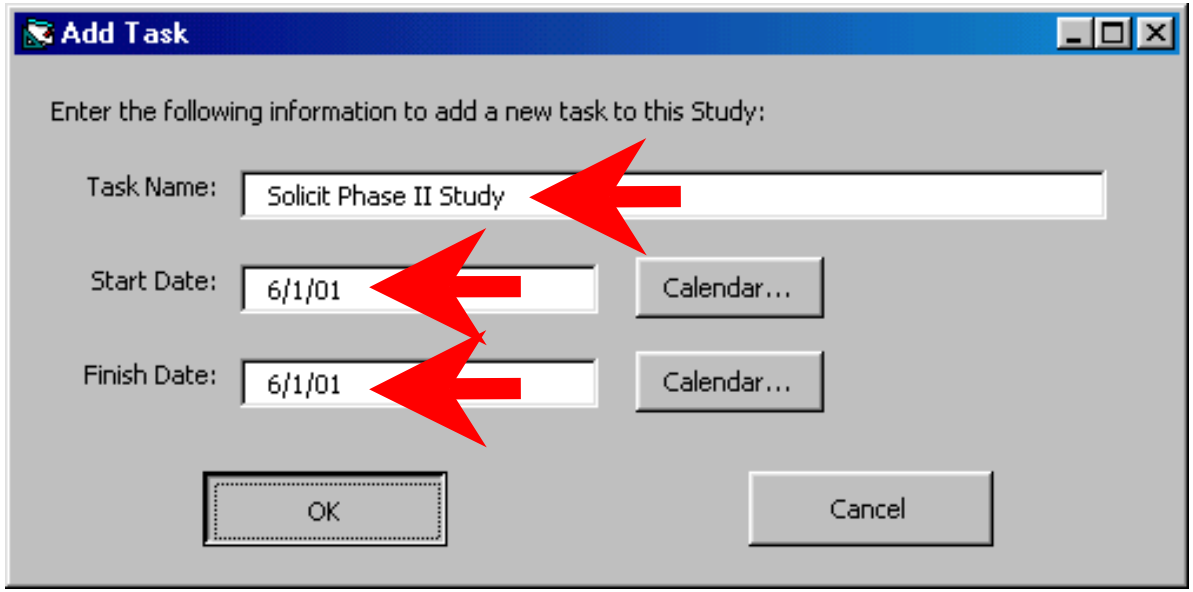
Tool Use

*The user must click on an existing task that is located just above the desired insertion location of the User-Defined Task. When the correct existing task is highlighted, the user should click on the **Add** button. This will open the Add Task dialog box.*

Adding User-Defined Tasks to a Gantt Chart

Scenario Element:

The CRS titles the task "Solicit Phase II Study" and types in the start and stop dates for the new task.



Tool Use

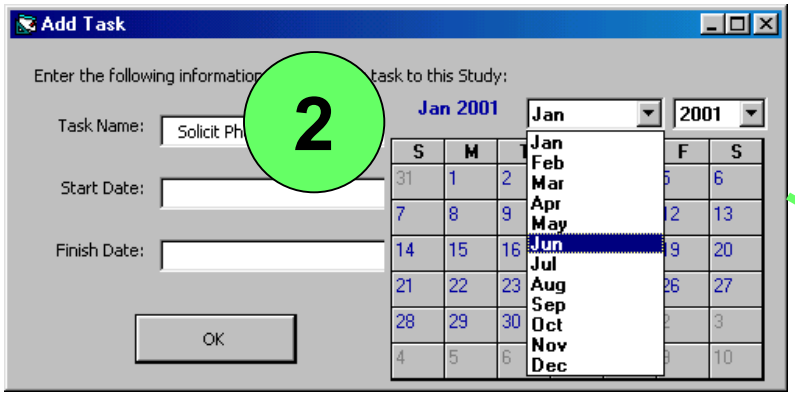
*The name of the new user-defined task should be typed in the **Task Name** box.*

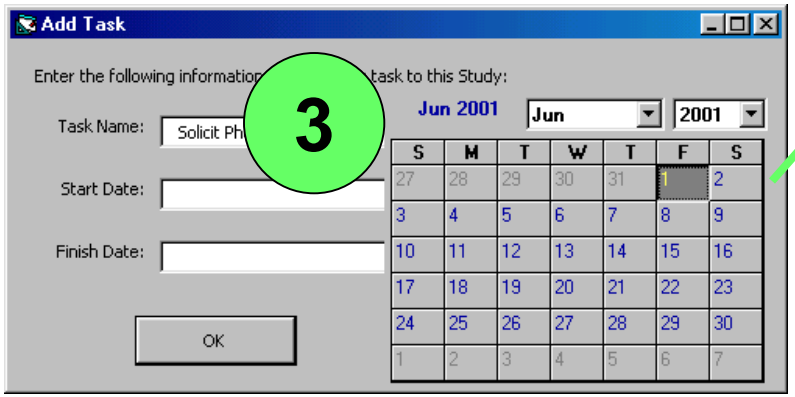
*The user must enter both a **Start Date** and a **Finish Date** for the User-Defined Task. MS Project cannot place the task in a Gantt chart without both a Start Date and a Finish Date. A task may have the same Start Date and Finish Date.*

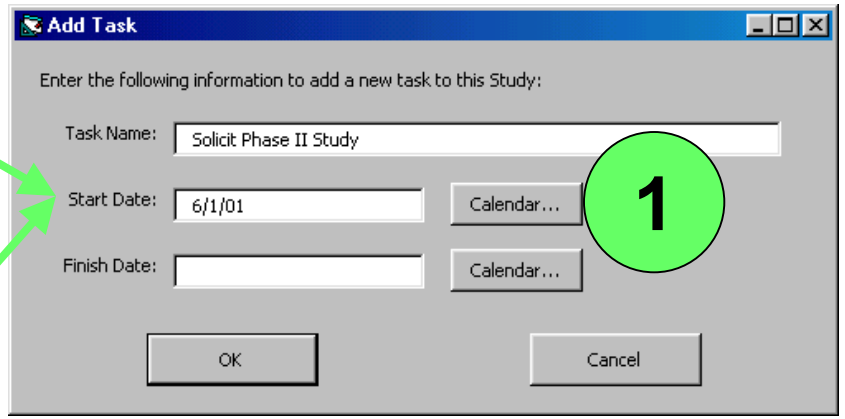
Adding User-Defined Tasks to a Gantt Chart

Tool Use

*The user may also click on the **Calendar** button to access a calendar that may be used to find a Start Date or a Finish Date.*



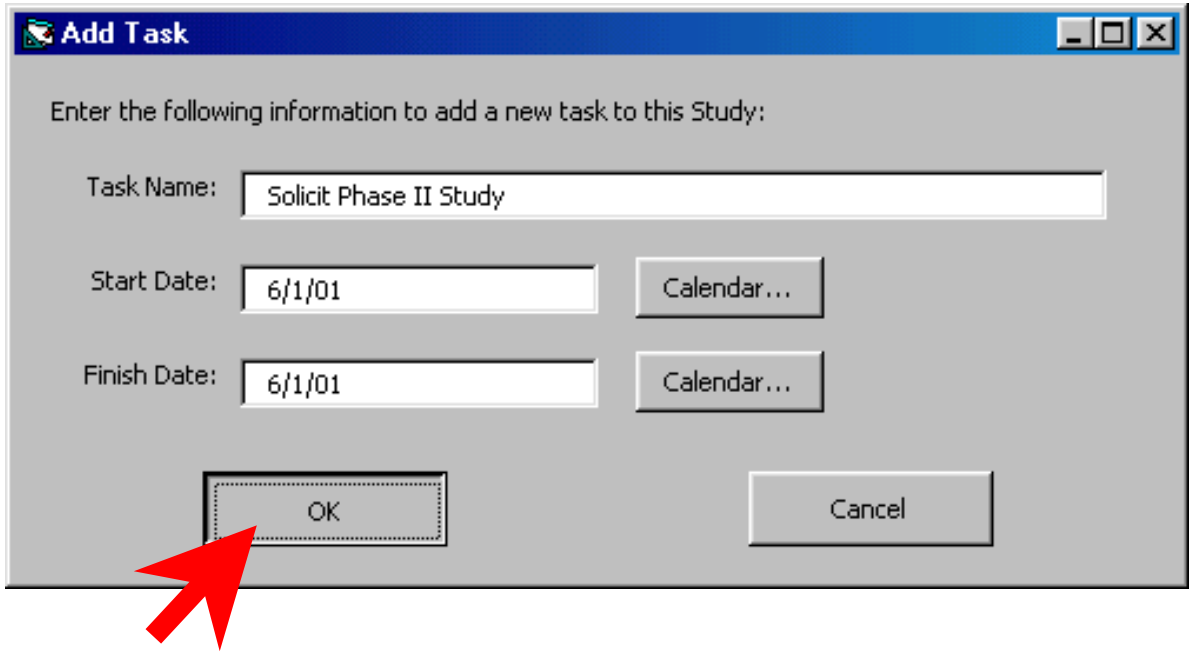




Adding User-Defined Tasks to a Gantt Chart

Scenario Element:

The CRS clicks OK to save the user-defined task to the database.



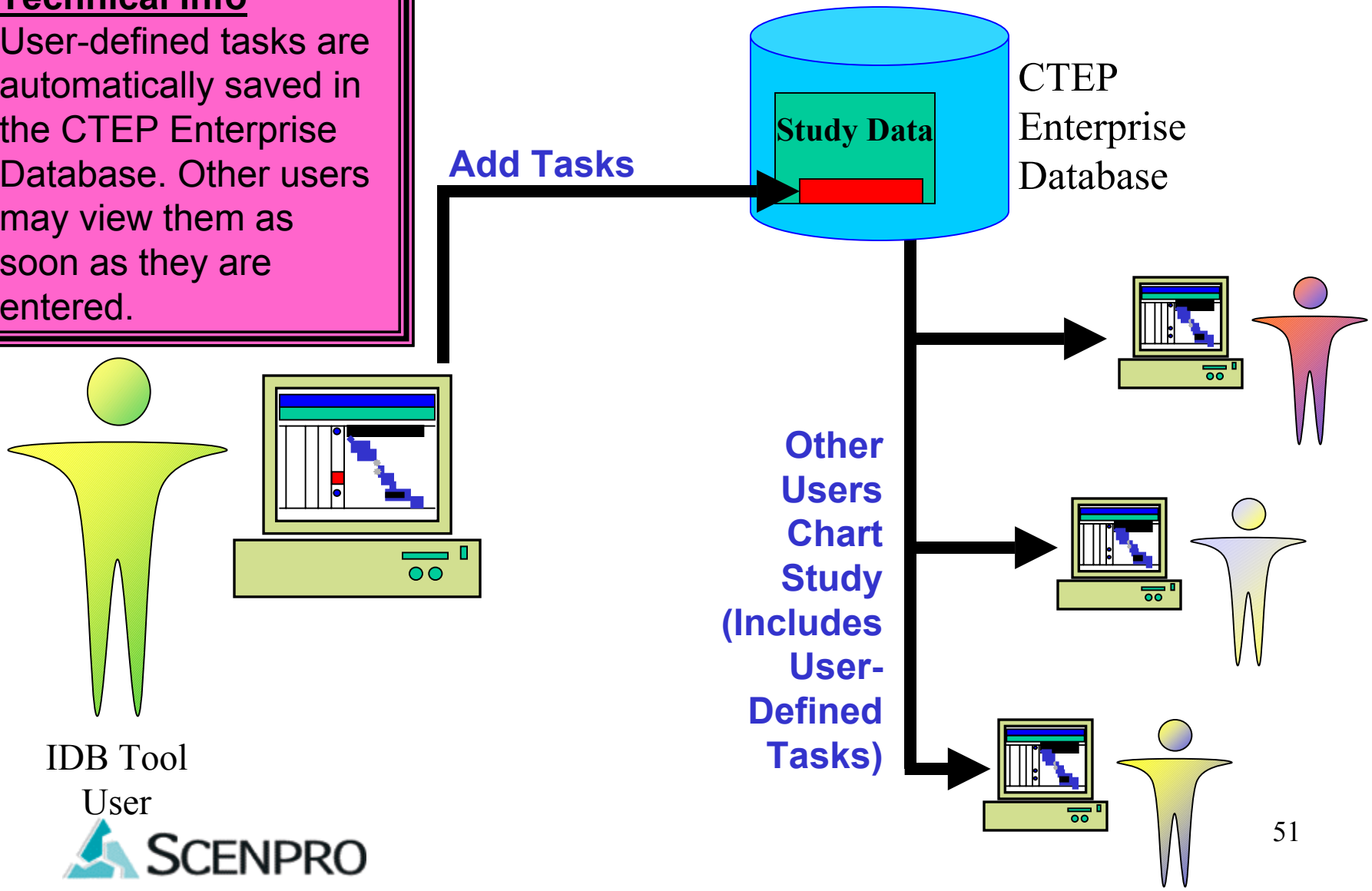
Tool Use

*When all information for the User-Defined Task has been entered, the **OK** button will save the new task, close the **Add Task** dialog box and return the user to the **User-Defined Task** dialog box. The **Cancel** button will close the **Add Task** dialog box without saving the new task.*

Adding User-Defined Tasks to a Gantt Chart

Technical Info

User-defined tasks are automatically saved in the CTEP Enterprise Database. Other users may view them as soon as they are entered.

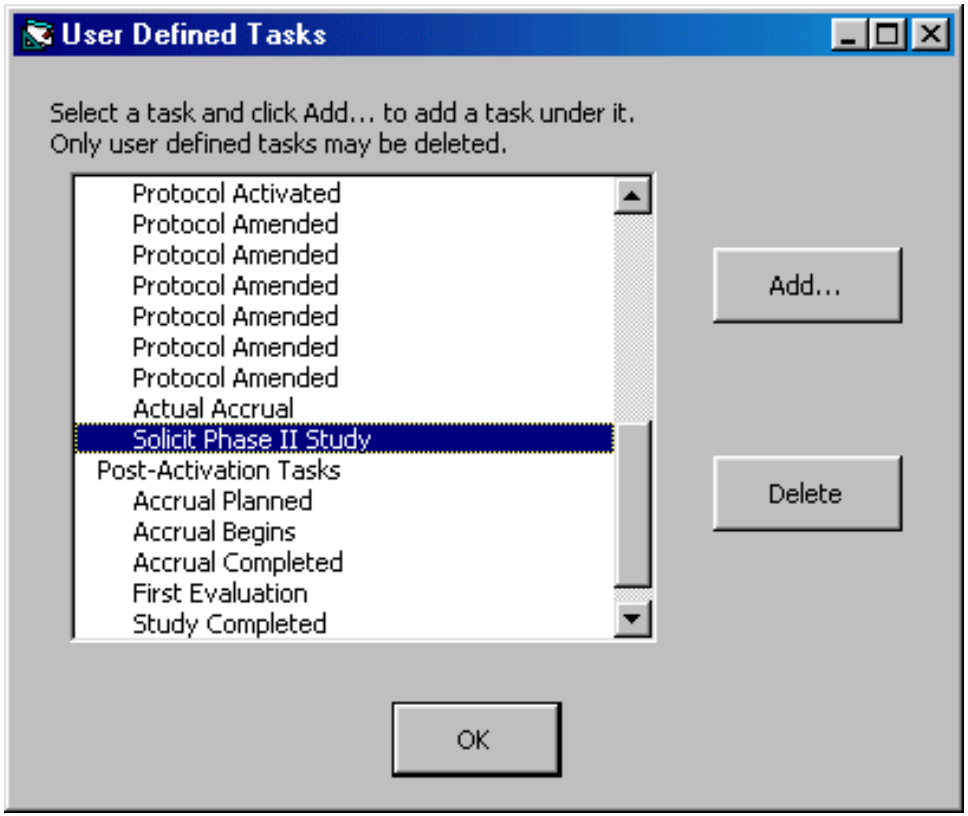


SCENPRO

Adding User-Defined Tasks to a Gantt Chart

Scenario Element:

The CRS verifies that the new task is displayed in the User-Defined Task window and clicks OK to return to the Gantt Chart display.



Tool Use

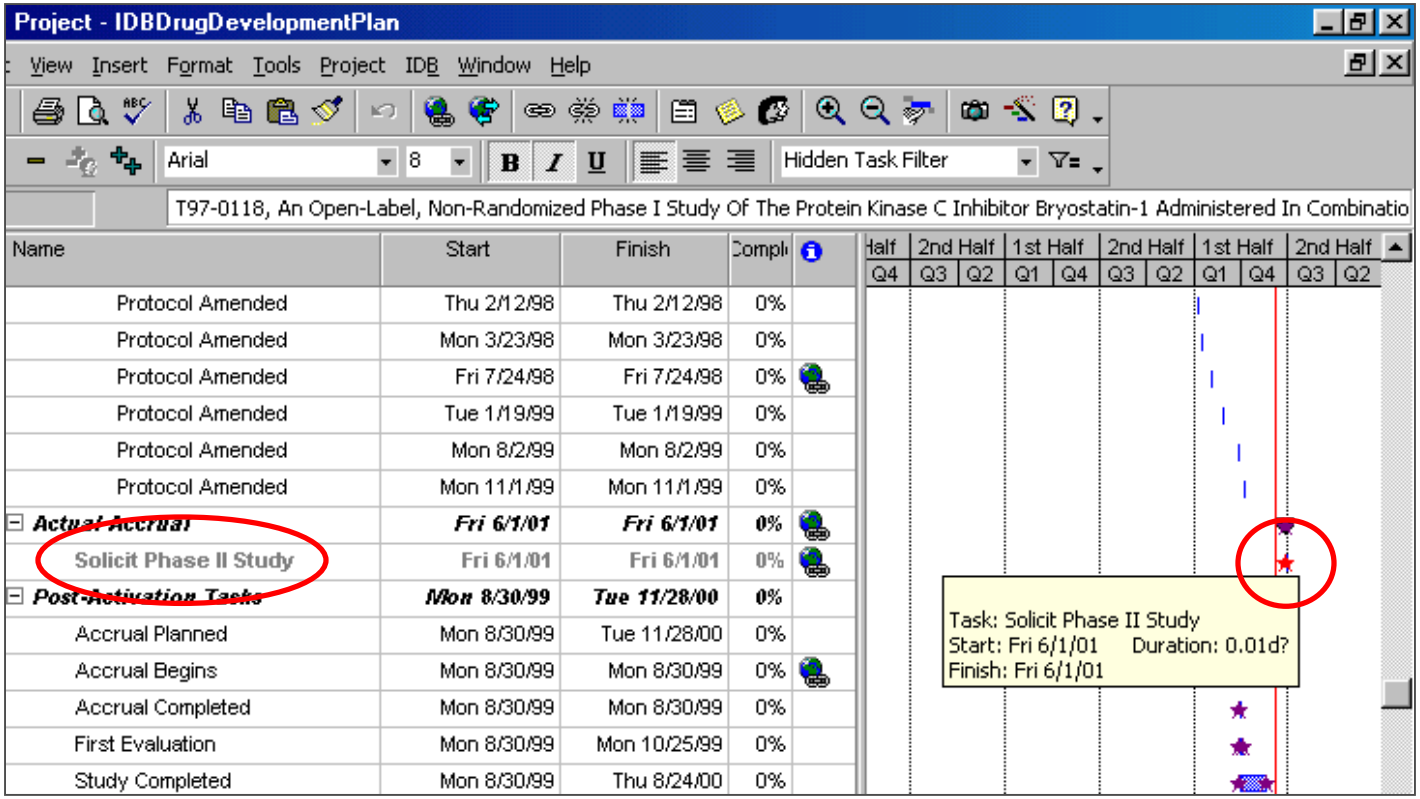
*The new task now appears in the desired location in the **User-Defined Task** window. The user may add another task by following the same procedure again. The **OK** button will close the **User-Defined Task** dialog box and return the user to the MS Project Gantt chart window.*

SCENPRO

Adding User-Defined Tasks to a Gantt Chart

Scenario Element:

The CRS verifies that the new task and its dates now appear in the Gantt Chart.



Tool Use

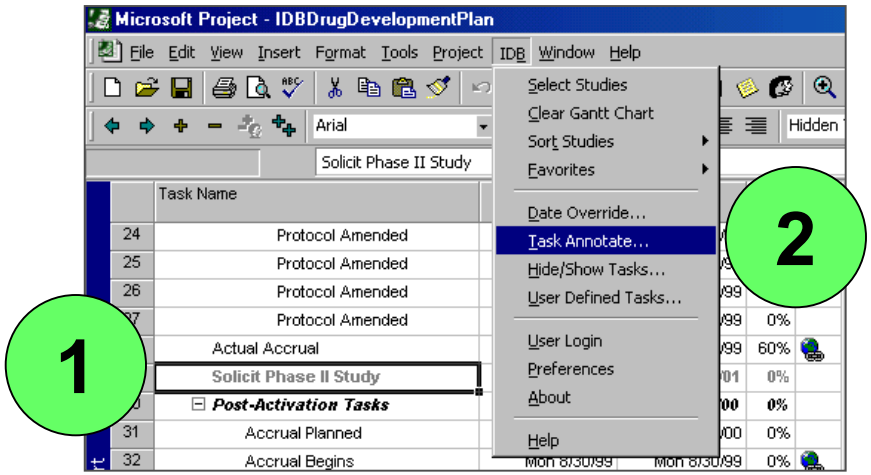
The names of user-defined tasks appear in gray text. User-defined dates appear in the chart as red stars.

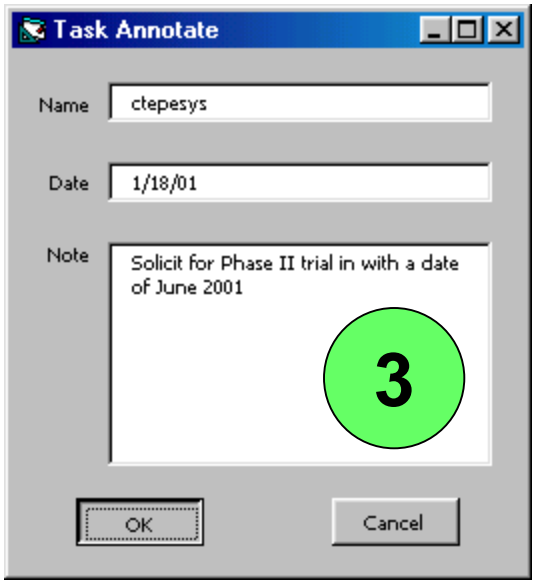
SCENPRO

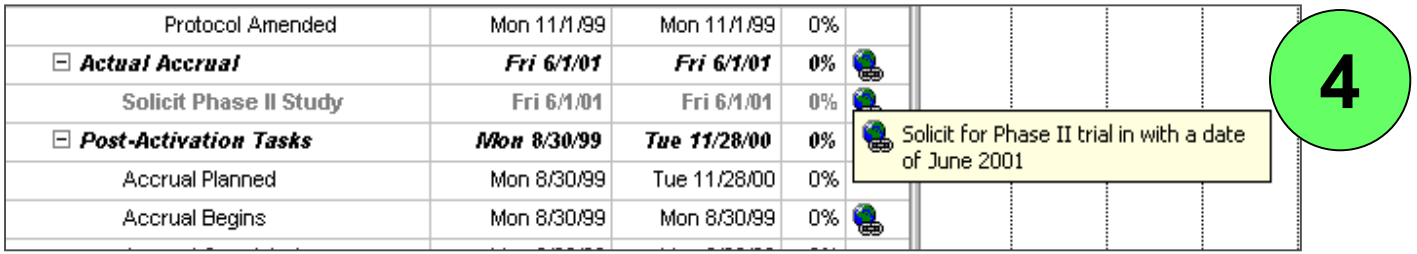
Adding User-Defined Tasks to a Gantt Chart

Scenario Element:

The CRS adds the following note to the new task: "Solicit for Phase II trial in with a date of June 2001."







SCENPRO

Investigational Drug Branch
Drug Development Plan Tool

Saving and Printing Gantt Charts

Saving a Gantt Chart as a Favorite

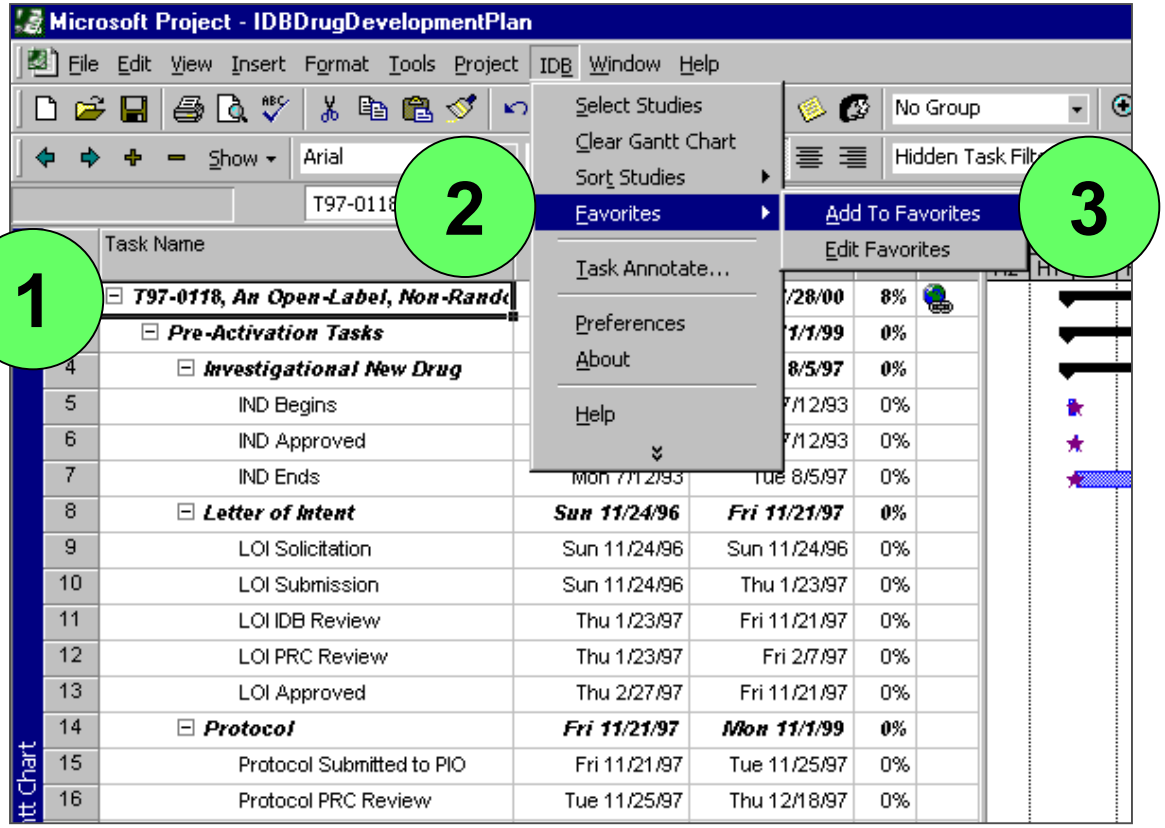
Scenario Element:

The CRS decides that she or he may need to view the Gantt chart for this study a number of time in the near future. The CRS also decides that a printout of the chart would be handy at an upcoming meeting.

Saving a Gantt Chart as a Favorite

Scenario Element:

The CRS chooses to save this study as one of his or her "Favorites" in order to chart it again easily in the future.



Tool Use

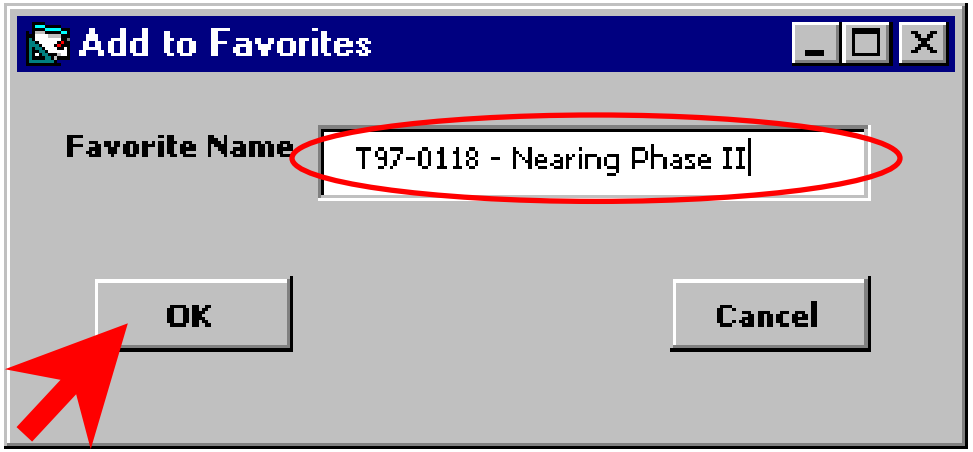
To save one or more studies as Favorites, the user should highlight the title of each study. If multiple studies are on the screen, the user can hold down the CTL key while clicking on study titles.

*The user should then select the **Add Favorites** command from **Favorites** item on the **IDB** menu.*

Saving a Gantt Chart as a Favorite

Scenario Element:

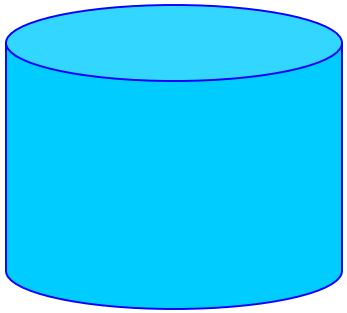
The CRS names this Favorite in a way that makes it quickly and easily recognizable.



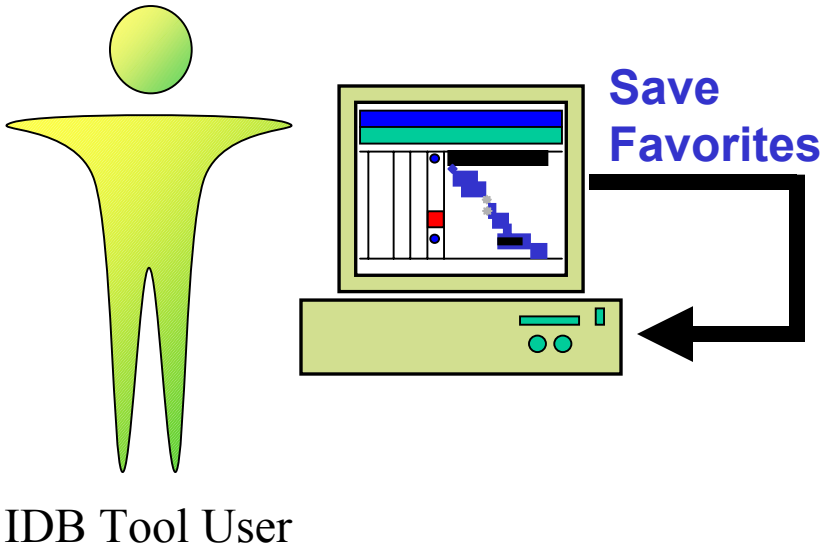
Tool Use

The user may give the Favorite any name he or she wishes and then click OK.

Saving a Gantt Chart as a Favorite



CTEP Enterprise Database

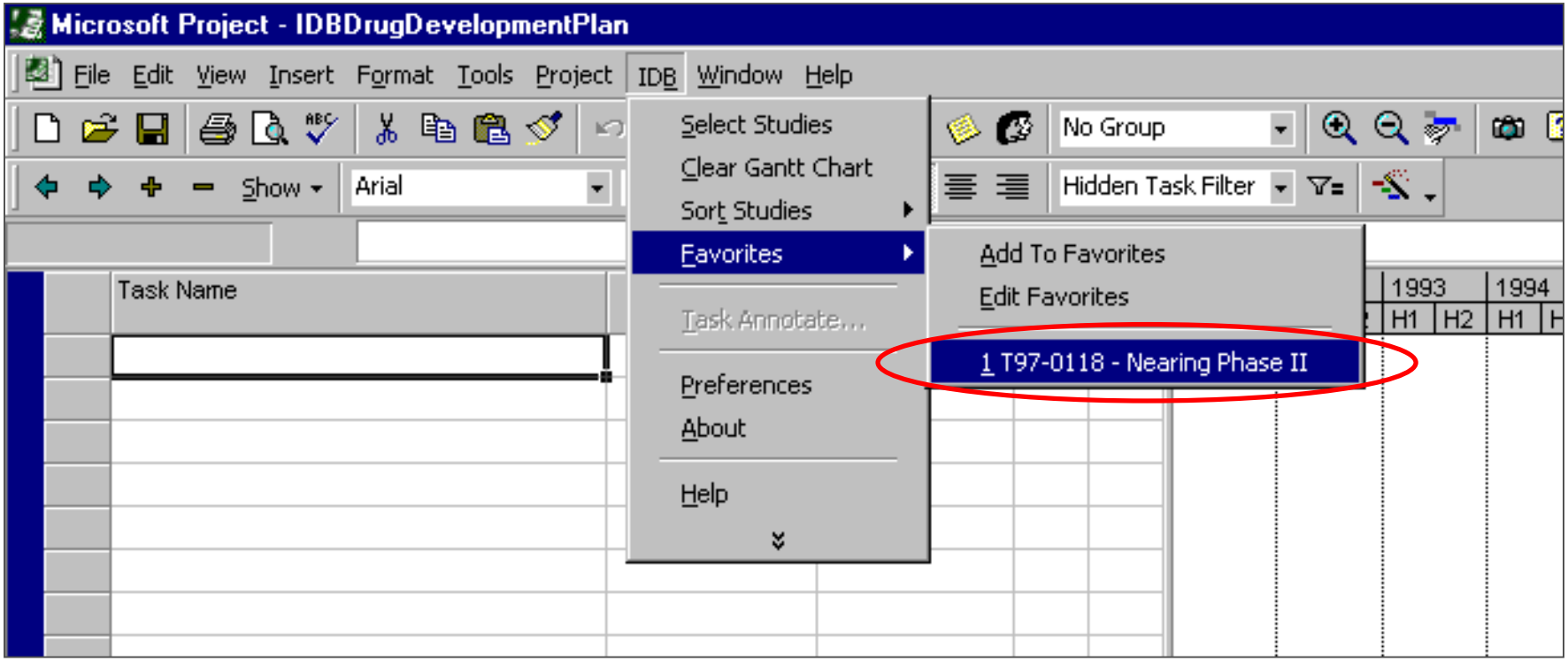


IDB Tool User

Technical Info

Each user's list of Favorites is stored on his or her own PC. The Favorites list is not stored on the CTEP Enterprise Database.

Saving a Gantt Chart as a Favorite



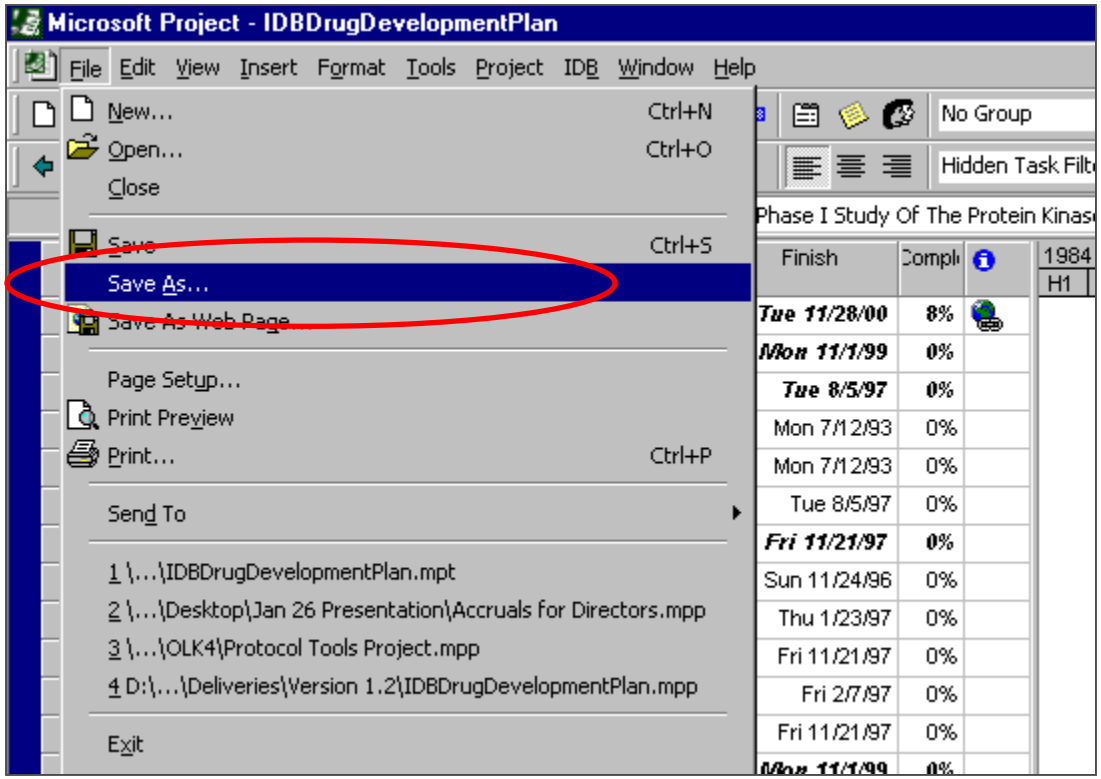
Tool Use

Once a Favorite has been named and saved, it appears on the favorites list. A saved Favorite may be re-charted with the latest data just by clicking on its name.

Each user may have a maximum of 10 Favorites. Favorites may be deleted by using the ***Edit Favorites*** *command.*

SCENPRO

Saving a Gantt Chart as a File



Tool Use

*The user may prefer to save today's view of the Gantt chart. The user may have formatted it in a specific way, or it may show data likely to change in the near future. In this case, the user may save the chart by using the **Save As** command from the **File** menu. This feature works just like any other Windows product.*

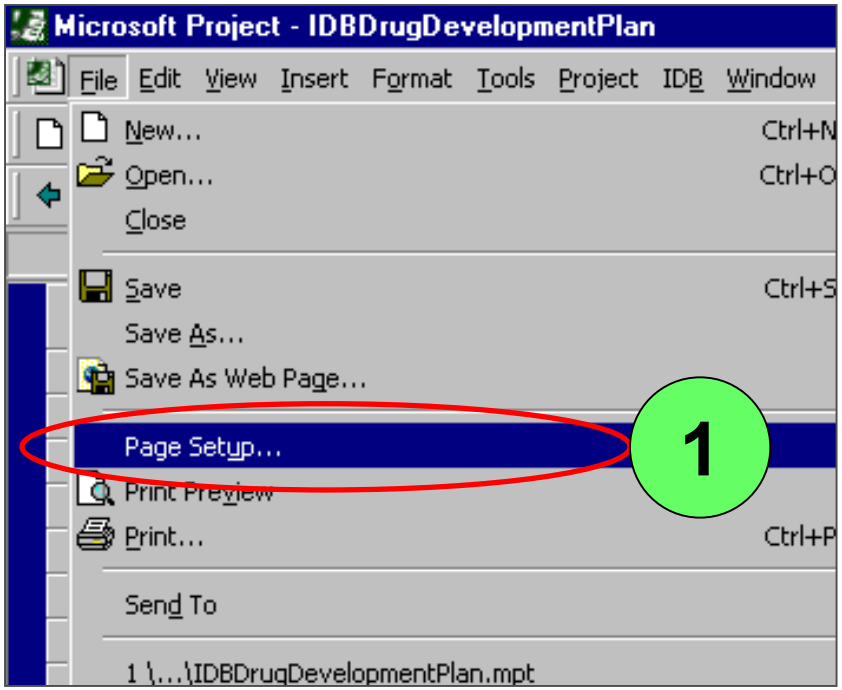
*The user must use **Save As** rather than Save. The IDB Drug Development Plan Tool will not allow the user to simply save the file, since that would change how the tool functions.*

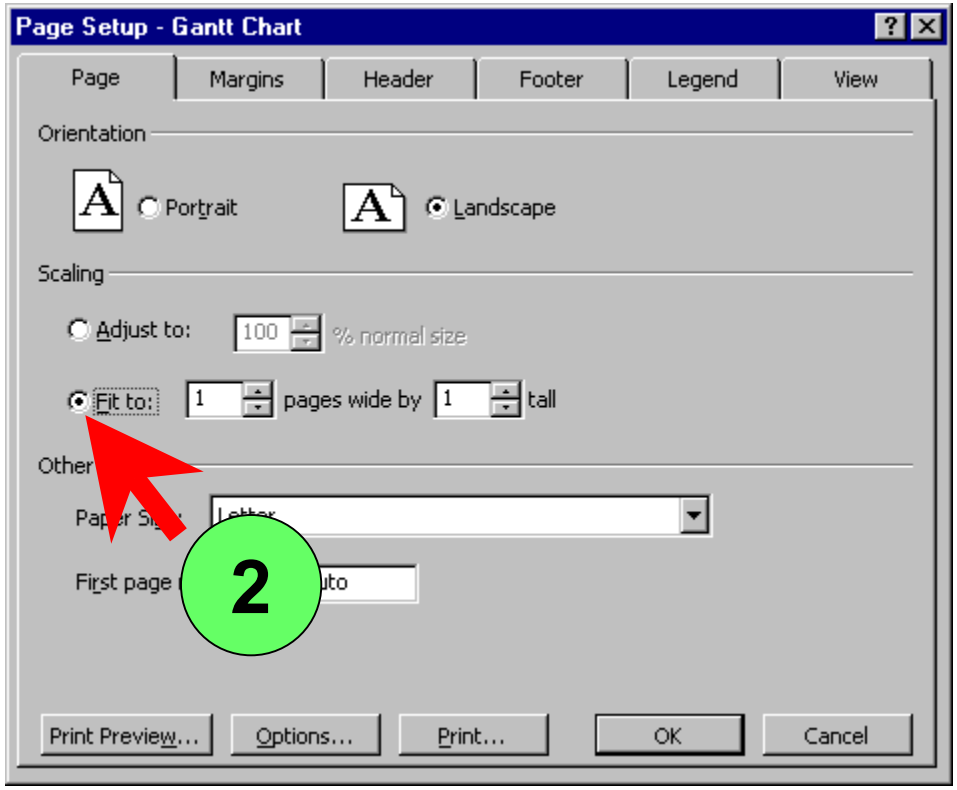
SCENPRO

Printing a Gantt Chart

Scenario Element:

The CRS sets up the Gantt chart so that it will print on a single page.





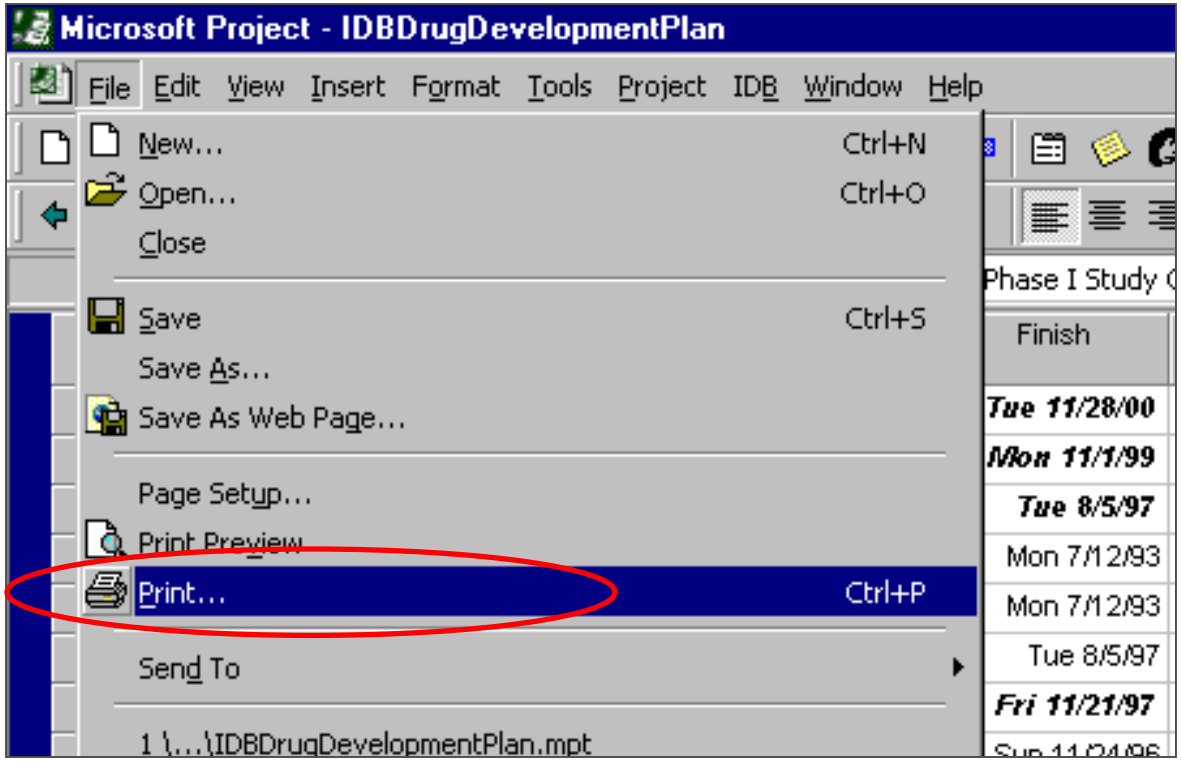
Tool Use

The user may set up a Gantt chart to print on a single page at the Page Setup dialog box.

Printing a Gantt Chart

Scenario Element:

The CRS prints the Gantt chart of study T97-0118 by using MS Project's regular print functions.



Tool Use

*The user may print a Gantt chart by using the **Print** command on the **File** menu.*

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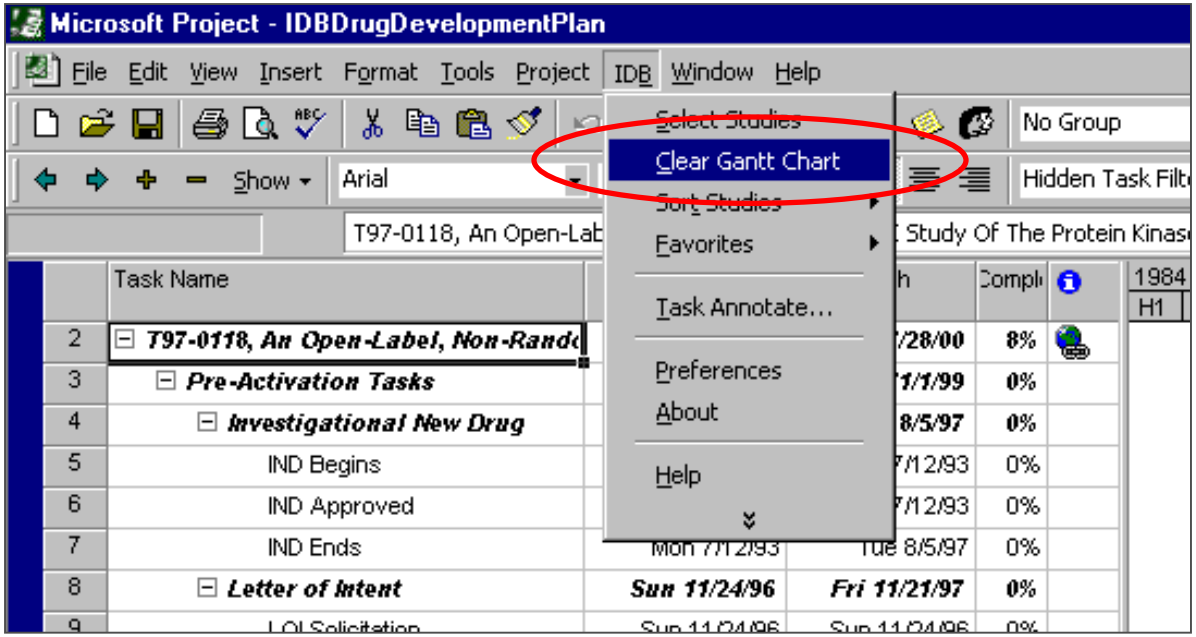
Investigational Drug Branch
Drug Development Plan Tool

Clearing the Gantt Chart
And Searching by Keyword

Clearing the Gantt Chart

Scenario Element:

The CRS is done with study T97-0118 and clears its Gantt chart from the screen.



Tool Use

*The user may clear a Gantt chart from the screen by choosing the **Clear Gantt Chart** command from the **IDB** menu.*

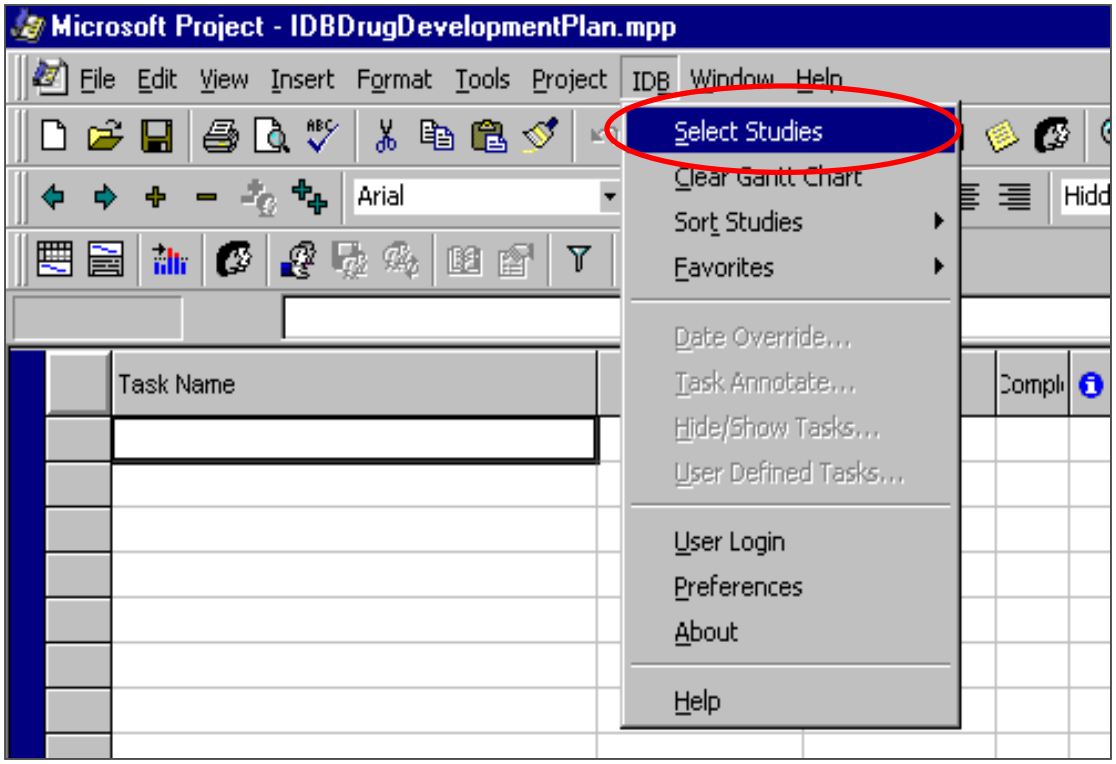
Technical Info

Clearing the Gantt chart does not affect any of the information that has been saved. It merely clears the Gantt chart from the user's screen.

Searching for Studies by Keyword

Scenario Element:

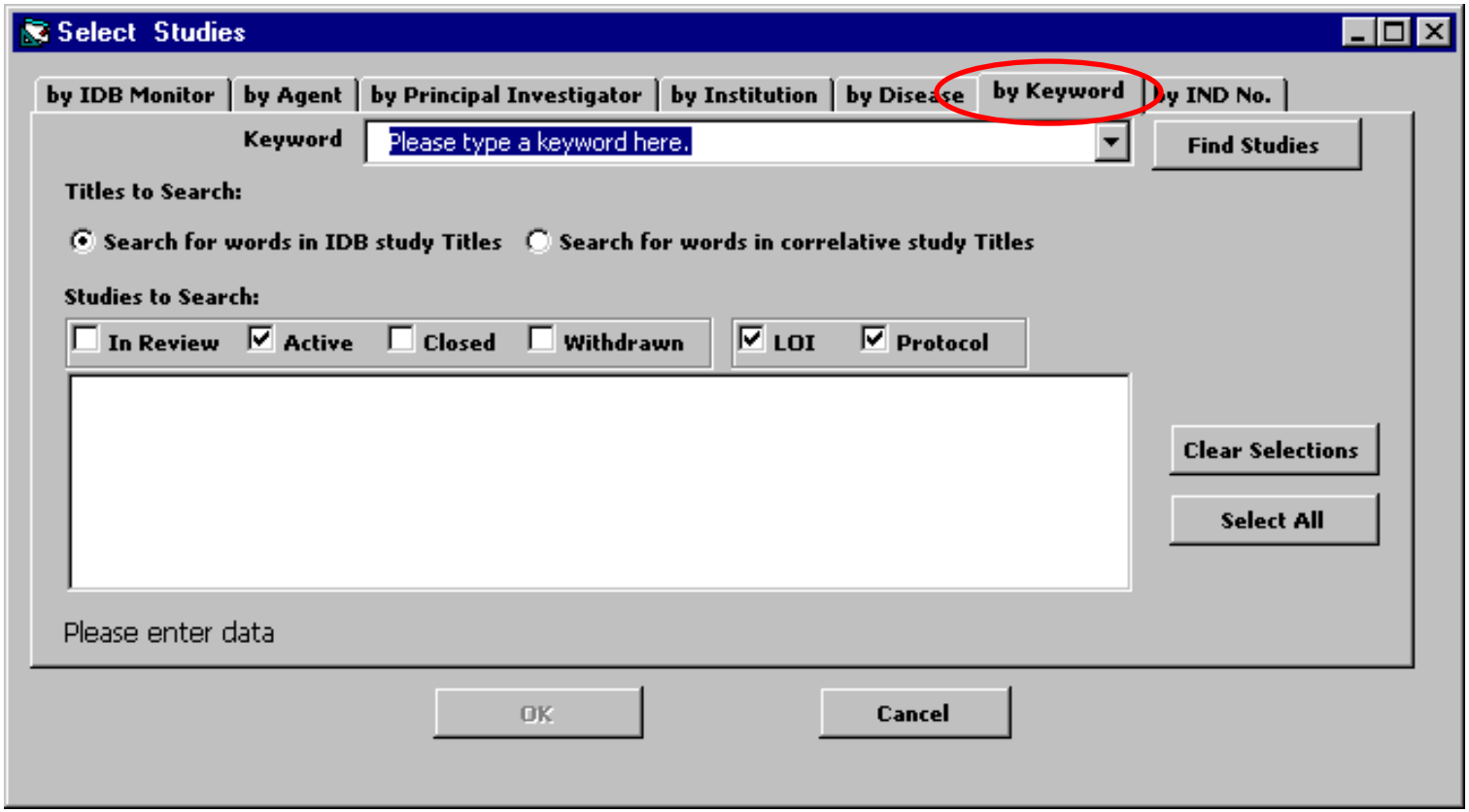
The CRS decides to carry out a search for imaging-related correlative studies that has been requested recently. The CRS chooses the "Select Studies" command.



Searching for Studies by Keyword

Scenario Element:

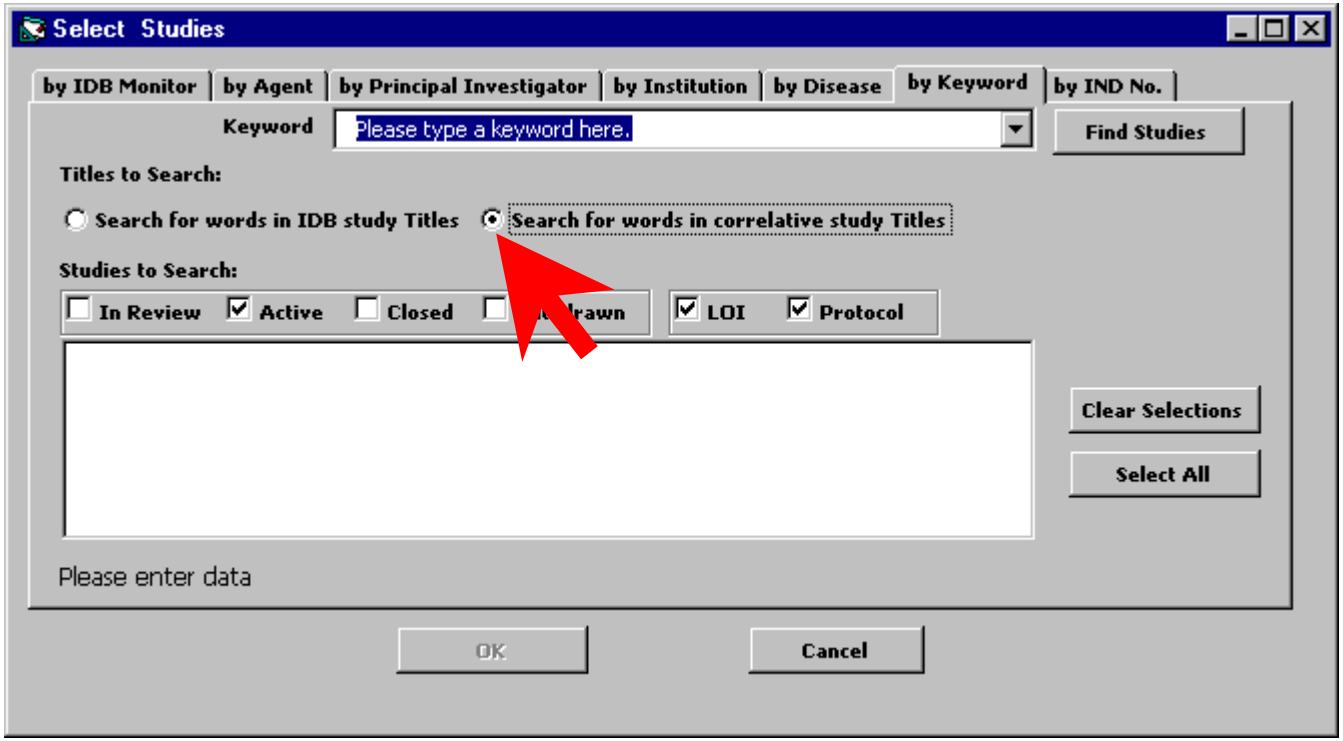
At the Select Studies dialog box, the CRS clicks on the "by Keyword tab.



Searching for Studies by Keyword

Scenario Element:

The CRS is searching for correlative studies, so she or he clicks clicks on the "Search for words in correlative study Titles" radio button.



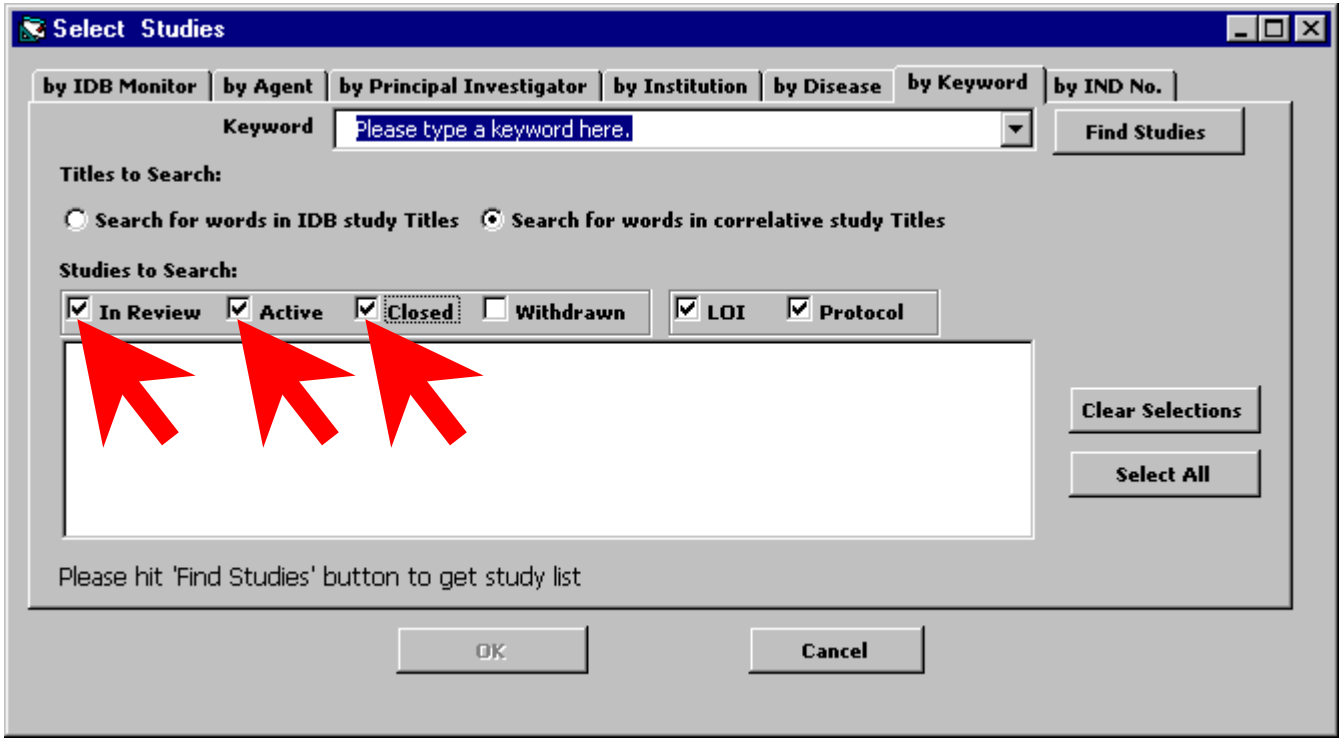
Tool Use

Users may search for studies in which a specified keyword appears in the study title. The user may search either regular study titles or the titles of correlative studies.

Searching for Studies by Keyword

Scenario Element:

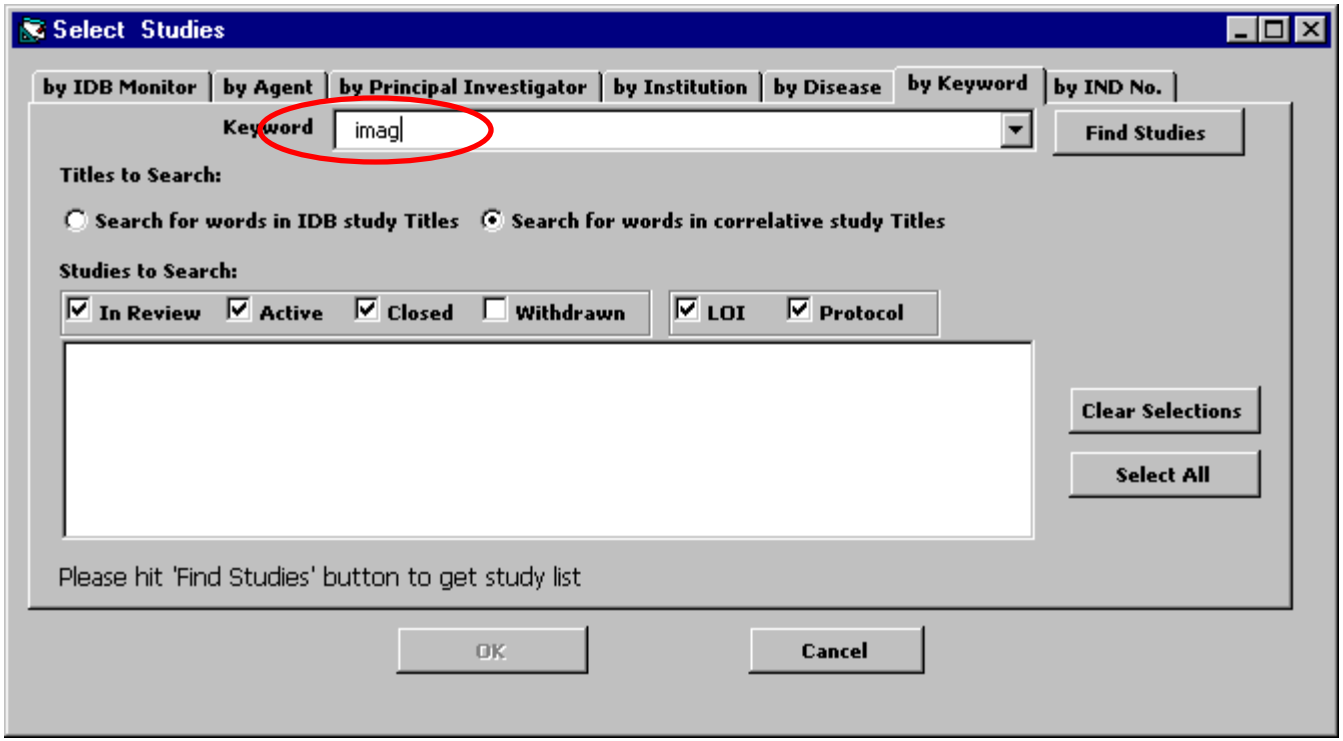
The CRS refines the search to include studies that are In Review, Active, or Closed.



Searching for Studies by Keyword

Scenario Element:

The CRS types the phrase "imag" in the Keyword box. Since this search is a text match, this phrase would match either "image" or "imaging." The CRS then clicks on the "Find Studies" button.



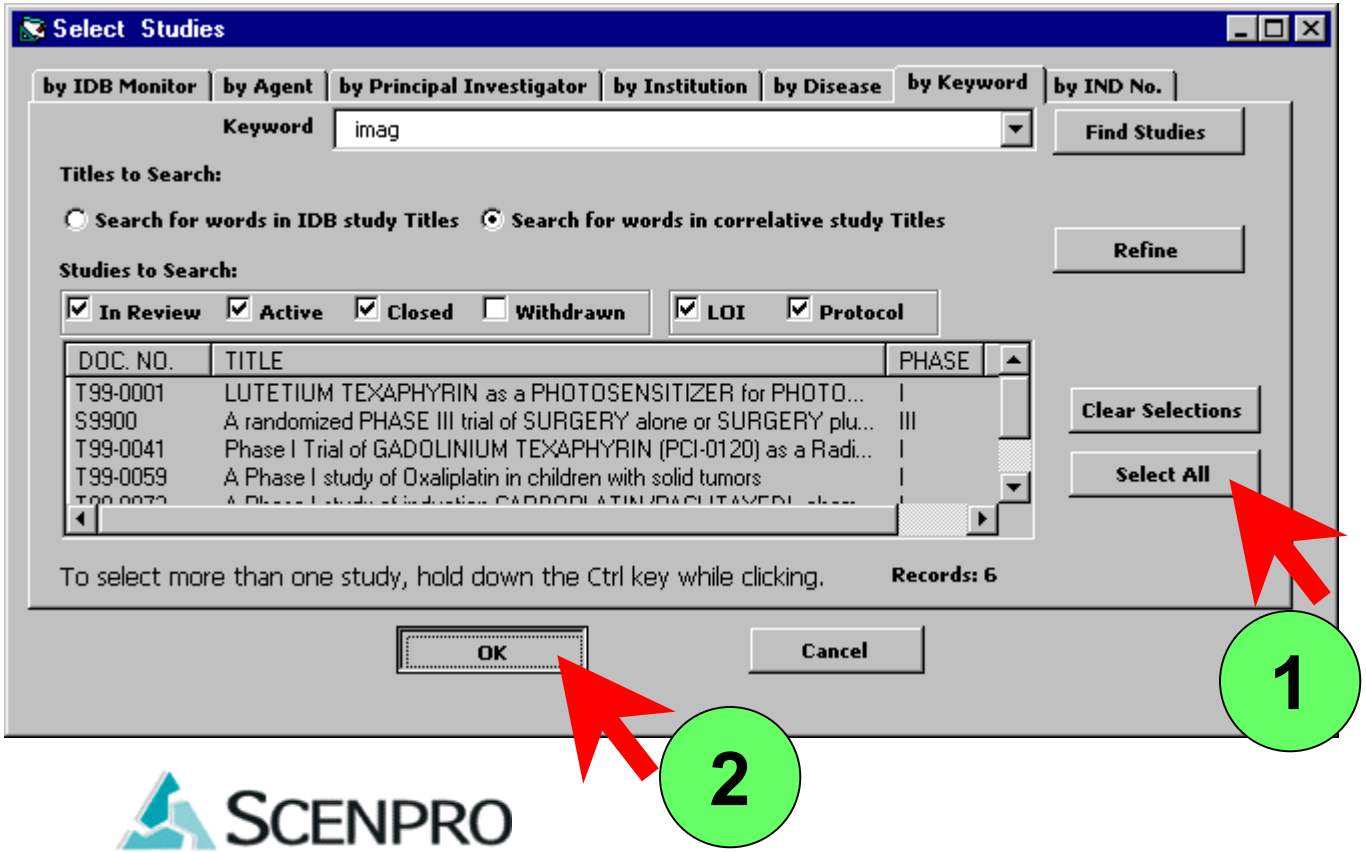
Tool Use

The keyword search is not case sensitive. However, it can only match a text string in a title. It does not allow complex search strategies such as those found on internet search engines.

Searching for Studies by Keyword

Scenario Element:

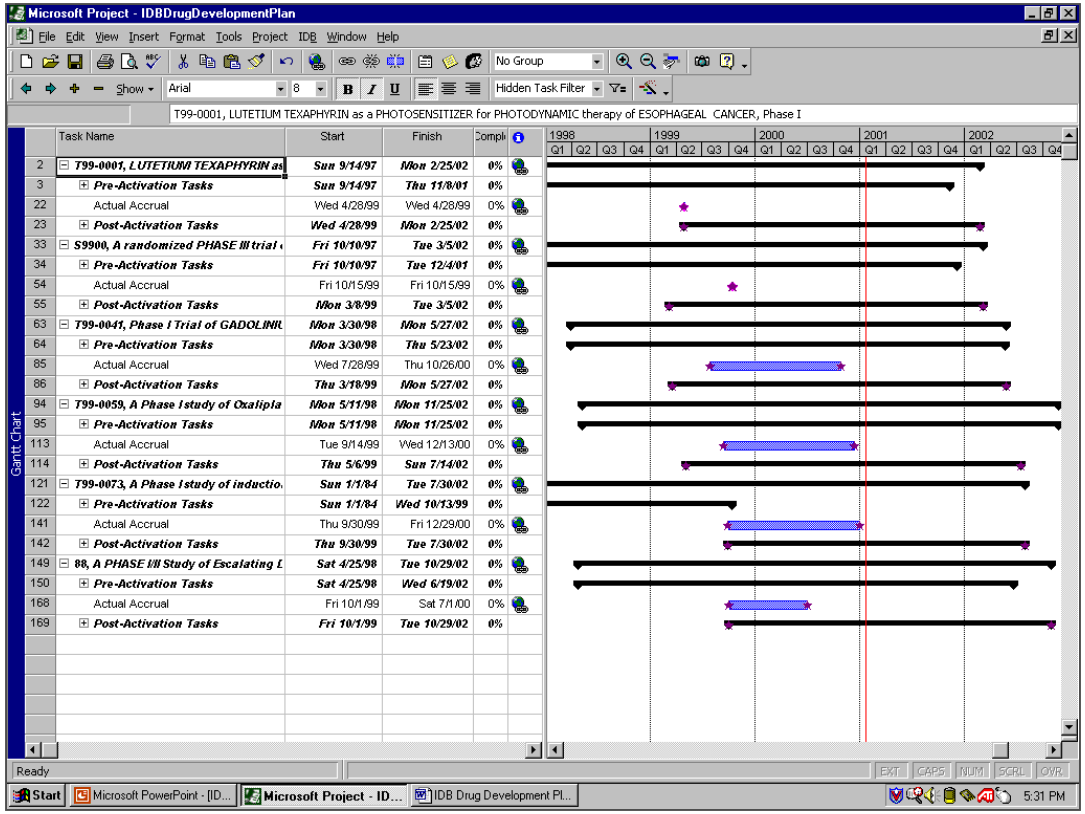
The IDB Drug Development Plan Tool returns six studies that meet the search criteria. The CRS clicks on the "Select All" button to select all six studies and then clicks the OK button to create a Gantt chart of them.



Searching for Studies by Keyword

Scenario Element:

The CRS reviews the studies that were charted and then saves them as a Favorite.



Tool Use

The user may chart multiple studies on the same Gantt chart. These studies may come from the same search or from several searches. The tool will continue adding new studies to the bottom of the Gantt chart until the user clears the chart.

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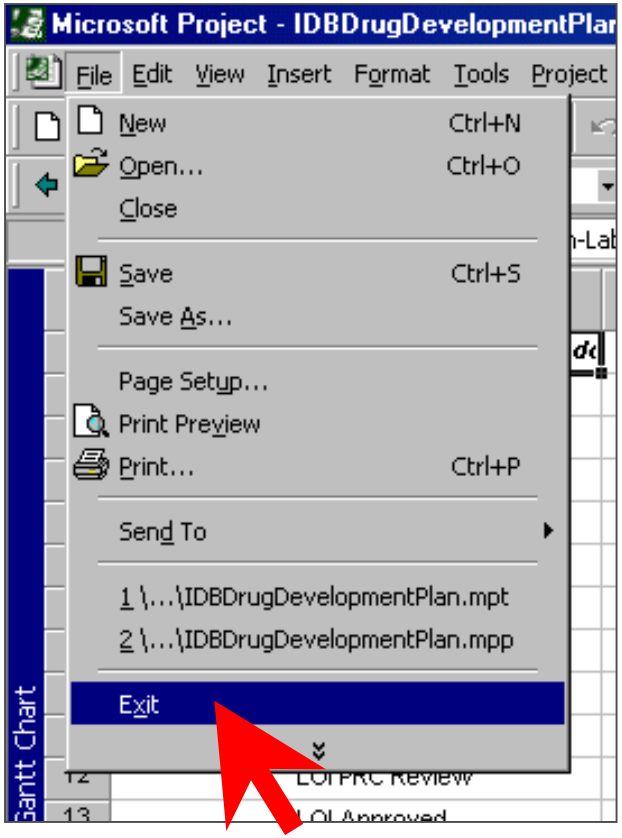
Investigational Drug Branch
Drug Development Plan Tool

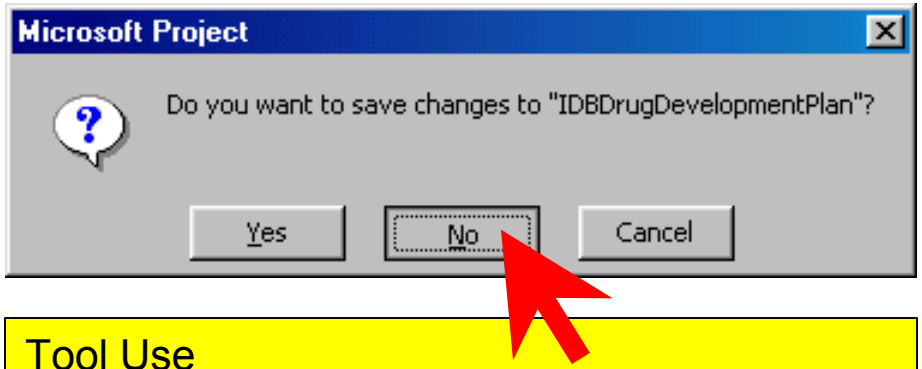
Exiting the
IDB Drug Development Plan Tool

Exiting the Tool

Scenario Element:

The Clinical Research Specialist is done working with the IDB Drug Development Plan Tool and selects Exit from the File menu.





Tool Use

Microsoft Project will ask the user to save changes to "IDB Drug Development Plan". Any user-added notes or new tasks have already been saved and require no additional action from the user.

It is best to answer "No" when prompted to save the file. If the user wishes to save a specific Gantt chart, he or she may use the "Save As" feature described earlier.

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Investigational Drug Branch
Drug Development Plan Tool

Where to Go to Report Problems

Reporting Errors and Asking Questions

Please report possible application errors, and questions about the data. It will be most helpful if you can write down any error messages and make a note of exactly what you were doing in the tool when the error occurred.

Please report errors and problems to:

ctephelp@ctisinc.com

Please send questions about using the tool and ideas for improvement to:

ncisupport@scenpro.com